IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

TRIAL BRIEF

Submitted by:

DEPUY MITEK, INC.

INTRODUCTION

Pursuant to this Court's Pretrial Order dated June 19, 2007, Plaintiff DePuy Mitek submits this Trial Brief.

The trial commencing on August 6 will solely address the issue of whether Defendants (collectively "Arthrex") infringe DePuy Mitek's Hunter 446 Patent. Other issues such as the validity of the Hunter 446 Patent, damages, and whether Arthrex's infringement was willful are not being tried in this phase of the case.

This case specifically relates to whether Arthrex's sale of its FiberWire sutures and suture products infringe claims 1, 2, 8, 9, and 12 of the Hunter 446 Patent under 35 U.S.C. §271(a). Also at issue is whether Pearsalls is liable for contributory infringement under 35 U.S.C. §271(c) by its making and importing of FiberWire sutures for Arthrex. Mitek will prove that the answer to both these questions is yes.

I. STIPULATIONS AND FACTS ESTABLISHED BY THE PLEADINGS

The facts that the parties have stipulated to are attached hereto as Exhibit 1.

II. ADDITIONAL FACTS WHICH WILL BE PROVEN BY PLAINTIFF

1. Mitek will prove that it owns the Hunter 446 Patent. (Mitek is asking for a pretrial ruling that it owns the patent, as set forth in more detail below).

2. Mitek will prove that the FiberWire suture has each and every element of the invention claimed in claims 1, 8, 9, and 12 of the Hunter 446 Patent.

3. Mitek will prove that the surface coating on the FiberWire does not materially affect the basic and novel properties of the invention, as defined by the Court. In particular, Mitek will prove that coating does not change that FiberWire is (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One (those yarns including a first set of

yarns selected from the group of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and a second set of yarns selected from the group of PET, nylon and aramid) - FiberWire has PE and PET, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

4. Mitek will prove that the suture Pearsalls provides to R.K. Manufacture, for resale to Arthrex, is especially adapted for use in Fiberwire and does not have any substantial noninfringing uses.

5. Mitek will prove that:

(1) Pearsalls sold or supplied;

(2) a material component of the patented invention that is not a staple article of commerce capable of substantial non-infringing use;

(3) with knowledge that the component was especially made or adopted for use in an infringing product.

In particular, Mitek will prove that:

(1) Pearsalls sells FiberWire suture to RK Manufacturing;

(2) The FiberWire suture that Pearsalls provides to RK Manufacturing (which is then sold to Arthrex for commercial sale as FiberWire) is a material component of FiberWire, and that RK Manufacturing does not alter the construction of the FiberWire suture provided to it by Pearsalls;

(3) Pearsalls knows that the suture it supplies to RK Manufacturing is especially made or adapted for use in the infringing FiberWire product.

6. Mitek will prove that the FiberWire suture that Pearsalls supplies to RK Manufacturing is not a staple article of commerce capable of substantial non-infringing use.

7. Mitek will also prove that Defendants' reverse doctrine of equivalents and tipping defenses have no merit, although Mite has requested a pre-trial ruling, as a matter of law, on these defenses.

III. PLAINTIFF MITEK'S CONTESTED ISSUES OF FACTS

1. Whether the NuSil surface coating on the FiberWire sutures materially affects the basic and novel properties of the invention?

2. Whether the suture that Pearsalls manufactures under an exclusive agreement with Arthrex knowing it to be specifically used for making commercial FiberWire sutures has any substantial noninfringing use?

IV. ARGUMENT

A. Mitek Will Prove that Arthrex Literally Infringes the Hunter 446 Patent

Direct patent infringement is the making, using, selling, offering to sell, or importing an invention covered by the claims of a valid patent without the authority of the patentee. 35 U.S.C. § 271(a). Determining whether a patent has been literally infringed involves two steps: (1) claim construction, followed by (2) a determination whether the properly construed claim encompasses the accused structure. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc). Claim construction is a question of law within the province of the Court. *Id.* at 979. This Court has already ruled on the meaning of the two claim terms at issue in this case, "PE" and "consisting essentially of."

Whether the properly construed claim encompasses the accused product is a question of fact for the jury to decide. *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347,

1353 (Fed. Cir. 2001). To establish infringement, Mitek must prove that each claim element is literally present in the accused product. *Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998). Mitek will prove that Arthrex sells FiberWire sutures and that its FiberWire sutures and suture products literally contain each and every limitation of claims 1, 2, 8, 9, or 12 of Mitek's Hunter 446 patent.

Mitek will establish that FiberWire suture has every element recited in the asserted claims of the Hunter 446 Patent. It is a sterilized surgical suture, composed of a heterogeneous braids of two continuous and discrete yarns formed of first and second fiber-forming materials, PE and PET, braided in intertwining contact. Mitek will prove that the silicone surface coating on FiberWire does not materially affect the basic and novel properties of the invention.

The Court has construed the basic and novel properties of the invention to be:

> (1) a surgical suture (2) composed of two dissimilar yarns from the lists in Claim One, (3) wherein at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

Mitek will show that the silicone coating on FiberWire is a surface coating and does not cause the yarns in the braid to adhere to one another. The coating does not affect the ability of the constituent elements of the suture – the PET and the PE – to contribute their properties to the suture. As explained in the Hunter 446 Patent, the optional surface coating may be used to "further enhance" certain properties of the suture.

B. Governing Law on Contributory Infringement

Defendant Pearsalls is also liable for contributory infringement of the Hunter 446 Patent under because it imports into the United States the braided PE/PET structure which is then sterilized and sold as FiberWire suture.

A finding of contributory infringement first requires a finding of direct infringement. Once direct infringement has been established, a party is liable for contributory infringement if the plaintiff can prove that: (1) the alleged contributory infringer sold or supplied; (2) a material component of the patented invention that is not a staple article of commerce capable of substantial non-infringing use; (3) with knowledge that the component was especially made or adopted for use in an infringing product. 35 U.S.C. §271(c). A "staple article of commerce capable of substantial non-infringing use" is something that has uses other than as a part or component of the patented product and that those other uses that are not occasional, farfetched, impractical, experimental or hypothetical. *MPT, Inc. v. Marathon Labels, Inc.*, No. 1:04-cv-2357 , 2007 U.S. Dist. LEXIS 3992, *21 (N.D. Ohio Jan. 19, 2007) (Ex. 2).

Mitek will show that Pearsalls indirectly infringes the Mitek's Hunter 446 Patent. Specifically, Mitek will show that Pearsalls' manufacturing of braided sutures that are sold as FiberWire products constitutes a contributory infringement of Mitek's Hunter 446 Patent under 35 U.S.C. §271(c). *See, e.g., DynaCore Holdings Corp . v. U.S. Philips Corp.*, 363 F. 3d 1263, 1275 (Fed. Cir. 2004) (quoting *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 442 (1984)). Specifically, Mitek will show that the unsterilized braided structure imported by Pearsalls is a material component of the accused FiberWire suture, that it has no substantial non-infringing use, and that Pearsalls imports it with the knowledge that it was especially made and adopted for use as a suture.

C. Governing Law on the Reverse Doctrine of Equivalents

Arthrex has suggested that, despite the Court's noted skepticism (Ex. 3 at 2-3) and the fact that Arthrex relegated it to a footnote in its summary judgment brief, it is may still pursue its "reverse doctrine of equivalents" defense.

The reverse doctrine of equivalents is a defense to patent infringement. Under this doctrine, which has never been upheld by the Federal Circuit, Arthrex might avoid infringement of Mitek's Hunter 446 patent by establishing that its FiberWire sutures, while literally meeting every limitation of the claims, are so far changed in principle from the invention as to operate in a manner that is the opposite of what is described in the Mitek's Hunter 446 Patent. *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc*., 279 F.3d 1357, 1368 (Fed. Cir. 2002) (*citing Graver Tank & Manufacturing Co. v. Linde Air Prods*., Co., 339 U.S. 605, 609 (1950)). Arthrex contends that, even though the Court expressly rejected its argument that "PE" as recited in the Hunter 446 Patent claims expressly includes ultra high molecular weight PE (UHMWPE), it uses PE in its FiberWire for a different purpose than the PE that is taught in the patent and, therefore, does not infringe under the reverse doctrine of equivalents.

Once Mitek proves literal infringement, Arthrex bears the burden of presenting a *prima facie* case that it does not infringe under the reverse doctrine of equivalents. *Sri Int'l v. Matsushita Elec. Corp. of Am*., 775 F.2d 1107, 1123-24 (Fed. Cir. 1985). The burden then is on Mitek to rebut this prima facie case and carry its burden of persuasion in establishing literal infringement. *Id*. at 1124. Mitek did so in its summary judgment brief (D.I. 106 at 10-12).

In accordance with its summary judgment briefing, Mitek is requesting a pre-trial ruling that this defense is without merit and is no longer part of this case.

V. OTHER OUTSTANDING ISSUES TO BE DECIDED BY THE COURT AND FOR WHICH MITEK REQUESTS RULINGS

A. Mitek Requests a Ruling That It Owns The Hunter 446 Patent

Mitek understands that Defendants are contesting that Mitek owns the Hunter 446 Patent. Based on the record evidence, there can be no dispute that Mitek owns the Hunter 446 Patent.

In February 1992, the inventors – Hunter, Taylor and Steckel, consistent with their employment obligation, assigned their rights in the invention to Ethicon, Inc. (Exs. 4-5).

Up until December 2003, Mitek was a subsidiary of Ethicon, Inc. (Exs. 6-7). In August 2004, Ethicon formally assigned to Mitek U.S. Patent No. 5,314,446 -- the Hunter 446 Patent (Ex. 8).

Under the present record, there can be no dispute that Mitek owns the Hunter 446 Patent, and Mitek, respectfully requests a ruling regarding the same.

Further, because Defendants' did not raise the defense of patent ownership in response to Mitek's motion of summary judgment of infringement, they have waived their ability to raise patent ownership as a defense to Mitek's infringement claim. *Pandrol USA, LP v. Airboss Railway Prods., Inc.,* 320 F.2d 1354, 1366 (Fed. Cir. 2003).

B. Mitek Requests A Ruling That Defendants' Failure To Preserve Evidence Entitles Mitek To An Adverse Inference Instruction That The Information Was Unfavorable to Arthrex

The pivotal issue in this case is whether the coating on FiberWire sutures has a material effect on the basic and novel characteristics of the claimed suture. Defendants retained at least two different experts and provided reports and testimony to support their position that the coating on FiberWire materially affects the novel and basic characteristics of the claimed invention.

- Dr. Gitis was retained to perform tests to evaluate the surface frictional properties of so-called "coated" and "uncoated" FiberWire.
- Dr. Burks was retained to perform a tactile feel test on so-called "coated" and "uncoated" FiberWire sutures.

As explained in more detail below, both experts failed to properly preserve data generated from or information relating to their tests. Under the circumstances, Mitek is entitled to an adverse inference jury instruction that the destroyed testing data or information was

unfavorable to Arthrex's position, and respectfully requests that the Court instruct the jury as follows:

> You have heard testimony about evidence which has not been produced. Counsel for plaintiff has argued that this evidence was in defendant's control and would have proven facts material to the matter in controversy.
>
> If you find that the defendant could have produced the evidence and that the evidence was within his control, and that the evidence would have been material in deciding among the facts in dispute in this case, then you are permitted, but not required, to infer that the evidence would have been unfavorable to the defendant.

1. The Law Supports Ruling That Mitek Is Entitled To An Adverse Inference Instruction

The Circuit has two prerequisites for showing entitlement to an adverse inference instruction – (a) knowledge about the litigation and (b) knowledge about the potential relevance of the destroyed information to the litigation. *Testa v. Wal-Mart Stores, Inc.*, 144 F.3d 173, 177 (1st Cir. 1998) (citing *Blinzler v. Marriott Int'l, Inc.*, 81 F.3d 1148, 1158 (1st Cir. 1996); *Anderson v. Cryovac, Inc.*, 862 F.2d 910, 925 (1st Cir. 1988); *Nation-Wide Check Corp. v. Forest Hills Distributors, Inc.*, 692 F.2d 214, 217-18 (1st Cir. 1982)). This Circuit has held "with some regularity" that a jury may infer from a party's "obliteration of a document relevant to a litigated issue that the contents of the document were unfavorable to that party." *Testa*, 144 F.3d at 177; *Blinzler*, 81 F.3d at 1159. "This permissive negative inference springs from the commonsense notion that a party who destroys a document (or permits it to be destroyed) when facing litigation, knowing the document's relevancy to issues in the case, may well do so out of a sense that the document's contents hurt his position." *Testa*, 144 F.3d at 177.

2. Defendants' Experts Conduct

Mitek satisfied the prerequisites for an adverse inference instruction. The record demonstrates that both Dr. Gitis and Dr. Burks knew:

(a) about the litigation because they were specifically retained in this matter to provide Rule 26 expert reports and testimony; and

(b) that their testing of so-called "coated" and "uncoated" sutures was relevant to the litigation because they were retained to opine about the effect of FiberWire's coating on the novel and basic characteristics of the invention.

a) Dr. Gitis' Test Data and Results Were Not Preserved

Dr. Gitis performed a series of tests that supposedly related to the surface friction properties of FiberWire so Defendants could purportedly show that FiberWire's coating materially affected the novel and basic characteristics of the Hunter 446 Patent's invention. Among the tests Dr. Gitis carried out, he performed two "tissue drag" tests, a clamp test and a needle test (Ex. 9 at 12). These tests were supposed to relate to the sutures' surface friction properties and to determine whether there were differences between the so-called "coated" and "uncoated" sutures. Dr. Gitis reported the results of the clamp test but did not report the results from his needle test in his expert report; nor were the data produced, as he testified that he destroyed the needle test data (Ex. 10 at 271:15-272:9). Dr. Gitis' explanation for destroying the needle test data is that the "results" were supposedly the "same" as the clamp test results (*id.* at 271:6-9; 271:23-272:5). But according to his testimony, he could not have compared them because he overwrote the data from the needle test with the clamp test data (*id.* at 271:10-272:9). Because Dr. Gitis destroyed the needle test data and results, Mitek did not have the opportunity to consider whether Dr. Gitis' needle test conflicted with his other tests or whether they supported Mitek's position rather than Defendants' position. Mitek is thus entitled to an adverse inference that the data were unfavorable to Arthrex's position.

b) Dr. Burks's Communications With Defendants' Counsel Were Not Preserved

Dr. Burks was provided with samples of so-called "coated" and "uncoated" FiberWire sutures so that he could perform a tactile feel analysis of the samples. After the analysis, Dr.

Burks sent an email to Defendants' counsel discussing his results (Ex.11 at 74:24-75:3). But neither Dr. Burks nor Arthrex ever produced that email (*id.* at 74:24-75:5), despite it being responsive to document requests and a subpoena served on Dr. Burks.

Under the circumstances, Mitek respectfully requests a ruling that the Court instruct the jury that it should draw an adverse inference from Arthrex's destruction of evidence. *Testa*, 144 F.3d at 178 (affirming negative inference instruction where there was sufficient prove that offender had notice of both a potential lawsuit and the destroyed documents relevance to the suit).

C. Mitek Requests A Ruling That Dr. Gitis' Supplemental Expert Report Be Excluded

1. Mitek is seeking a ruling excluding Dr. Gitis' Supplemental Expert report for failing to comply with the Court's January 31, 2007 Order (D.I. 104)

Dr. Gitis is an Arthrex expert who carried out laboratory testing purporting to show that the coating on FiberWire materially affects the basic and novel properties of the invention. As expert discovery was closing, and after Mitek's expert had exposed problems with Dr Gitis' testing as set forth in his expert report, Arthrex's counsel informed Mitek's counsel that Dr. Gitis was re-doing his testing as a computer virus may have affected his test results. Mitek moved the Court for an Order directing that Arthrex prove the existence of the virus, and that it had actually affected Dr. Gitis' test data, before Arthrex could "re-do" Dr. Gitis' report. After Mitek filed its motion showing that the errors in Dr. Gitis' report could not have been virus related, Defendants changed their position. Defendants' counsel represented to the Court that some of the errors were virus related but that there were also "typographical errors in reporting the diameter of the suture tested . . . and in reporting the speed with which the knot slippage strength testing was

performed" (D.I. 91 at 3). Based on this, Defendants argued that Dr. Gitis should be permitted to supplement his report.

The Court's January 31, 2007 Order permitted Dr. Gitis to supplement his expert report but "only to the extent necessary to correct *typographical* and *computational errors* unrelated to the computer virus" (D.I. 104 at 2, emphasis added). Dr. Gitis did supplement his report, in June 2007. In the Supplemental Report, Dr. Gitis changed the stated diameter of the suture tested, the speed at which the knot slippage strength testing was performed, and the description of his pliability test. However, at his Court-ordered deposition last week, Dr. Gitis testified that his June 2007 Supplemental Report *did not correct typographical or calculation errors* (Ex.12 at 20:17-21:10; 25:15-26:5). Dr. Gitis testified that the reported speed for the knot slippage strength test in his original report was neither a typographical error nor a computational error but a mistake (*id.* at 28:23-30:7). Likewise, Dr. Gitis admitted that his description of the pliability test in his original report, as being performed with a uniform increasing load rate, was neither a typographical nor a computational error (*id.* at 20:17-21:10). In fact, he admitted that the mistake arose because he did not "pay enough attention" (*id.* at 24:9-23). Dr. Gitis also candidly testified that he could not say with certainty that the diameter measurement provided in his original report was a typographical error (*id.* at 25:15-27:13; 63:2-64:2). Yet, his June 2007 Supplemental Report changed each of these items, in contravention of the Court's January Order.

Mitek's counsel discussed these issues with Defendants' counsel on July 20, 2007, but could not resolve the matter.

Because Dr. Gitis' Supplemental Report is clearly outside the scope of what was allowed by the Court's January Order, Mitek requests an order excluding the Supplemental Report or any testimony about the data therein.

D. Mitek Requests a Ruling that an Improperly Withheld Communication Between Defendants' Counsel And Dr. Gitis Be Produced

At Dr. Gitis' deposition, a document involving Dr. Gitis was identified as being withheld for relevancy reasons or based on an objection to either Dr. Gitis' subpoenas or Mitek's document requests to Arthrex (Ex. 12 at 7:4-8:2; *see e.g.*, Exs. 13-14 and Ex. 15 at Request Nos. 48, 49, and 52). Arthrex's counsel stated on the record that the document was a communication from counsel to Dr. Gitis and that it "goes directly to the virus" (Ex. 12 at 7:4-8:2). Mitek is not aware of any basis for withholding a communication with a testifying expert on the basis of relevancy. In any event, the document is potentially highly relevant as it bears directly on the credibility of Dr. Gitis and his testing, since a year ago he was alleging that all of his data were potentially corrupted by a "virus," and he is now taking a contrary position, and apparently intends to produce test data he once represented was corrupt..

Mitek's counsel discussed this issue with Defendant's counsel on July 20, 2007, and asked counsel for legal authority to support their position. But no authority was provided, nor has the document been provided to Mitek. Mitek requests an order directing Arthrex to immediately produce the withheld communication.

E. Mitek Requests a Ruling Limiting Arthrex's Proofs In View of Improper Instructions Not to Answer at Dr. Gitis' Deposition

At his Court-ordered deposition on July 18, Dr. Gitis was instructed not to answer numerous questions pertaining to the credibility of the data and opinions in his opening expert report. His July 18 deposition was Mitek's only opportunity to question Dr. Gitis about the alleged virus because Defendants failed to comply with Mitek's requests for evidence that a virus actually corrupted Dr. Gitis' data. At the deposition, Mitek posed various questions in response

to the allegations made by Arthrex a year ago that Dr. Gitis' data may have been corrupted by a computer virus, but Dr. Gitis was only permitted to answer select questions.

Examples of the questions and instructions not to answer are:

> Q. What hardware was infiltrated by your --what specifically was it by this virus that you believe happened? Was it hardware attached to the equipment that was running the test?
>
> MR. TAMBURO: Objection, outside the scope and asked and answered.
>
> THE WITNESS: Shall I answer?
>
> MR. TAMBURO: Asked and answered.
>
> THE WITNESS: So I -- first of all, it is not that I believed that there was a virus. It is a fact that there was a virus. It is a fact that we had a virus. It is not a belief, but I do not know and I didn't know at that time whether it infiltrated lap computers or what computers have been infiltrated inside the company, I do not know.
>
> BY MR. BONELLA: What was the name of the virus?
>
> MR. TAMBURO: Objection. Do not answer, beyond the scope. I instruct him not to answer.

(Ex. 12 at 49:15 - 50:14).

> BY MR. BONELLA: Q. Can you describe generally how the virus worked?
>
> MR. TAMBURO: Objection. Same objection. Instruct him not to answer, since it is beyond the scope of the Court's order.
>
> THE WITNESS: I am not an expert in viruses.
>
> BY MR. BONELLA: Q. Isn't it true that there was no virus that affected your data or your report?
>
> MR. TAMBURO: Objection, argumentative and beyond the scope of this deposition. And I'm instructing you not to answer.
>
> BY MR. BONELLA: Q. Sitting here today, do you believe you had a virus that infiltrated the data in the report or not?
>
> MR. TAMBURO: Same objection. Instructing you not to answer, beyond the scope of the Court's order and the deposition.

(*id.* at 51:8-52:6).

> Q. As of July 14, 2006, you thought you had a software virus that would cause you to want to redo all your tests; right?
>
> A. That's correct.
>
> Q. And you have no documentation or anything regarding that virus?
>
> MR. TAMBURO: Objection, beyond the scope, instructing you not to answer. I am instructing you not to answer.

(*id.* at 53:8-16).

> Q. Did you ever provide specifics regarding the virus that you believe may have infected your system to counsel?
>
> MR. TAMBURO: Objection, beyond the scope, instructing the witness not to answer.

(*id.* at 68:4-9).

Because of these repeated, improper instructions not to answer, Mitek was denied the opportunity to test the veracity of Arthrex's representations about the computer virus allegedly infecting Dr. Gitis' data or to test the credibility of Dr. Gitis and his test data and opinions. Arthrex should not be permitted to come to trial and now allege that Dr. Gitis' data were untouched by a virus or, if they were affected, to try to present evidence of how they were affected.

Dr. Gitis was also instructed not to answer questions about information he was unable to explain at his first deposition (*See, e.g.*, Ex. 12 at 143:7-13; 229:16-20; 236:3-9; 237:8-12; 241:10-11; 242:16-243:4; 261:10-14; 263:14-265:6; 261:1-9; 268:1-269:5). And Dr. Gitis' supplemental report did not address the unexplained information from his first deposition. Concerned that Dr. Gitis would attempt to "supplement" his explanations live at trial, Mitek asked Dr. Gitis about some of the unexplained information at his recent July 2007 deposition.

But Dr. Gitis was instructed not to answer Mitek's questions (*See, e.g.*, Ex. 12 at 64:3-66:25; 118:18-121:12; 132:8-19).

Mitek requests an Order directing that Dr. Gitis may not offer any explanation at trial regarding the virus allegations beyond the scope of his testimony at his July deposition, nor may he offer any testimony beyond the scope of his expert reports or depositions.

F. Mitek Requests Rulings On Defendants' Tipping And Reverse Doctrine Of Equivalents Defenses

At the June 19, 2007 summary judgment hearing, the Court indicated that it may resolve Arthrex's "tipping" and reverse doctrine of equivalents defenses on summary judgment (Ex. 3 at 3:2-5:7).

Because these defenses require additional proofs in rebuttal, particularly on the reverse doctrine of equivalents defense, Mitek respectfully requests a ruling as a matter of law on these matters so it can prepare accordingly for trial.

G. Mitek Requests Rulings On Its Motions in Limine

Presently before the Court are Mitek's Motions in *Limine*, including:

(1) Mitek's Motion *In Limine* (No. 1) and Memorandum in Support to Exclude Evidence Regarding CETR Testing (D.I. 117 and D.I. 118);

(2) Mitek's Motion *In Limine* (No. 2) and Memorandum in Support to Preclude Arthrex from Presenting Evidence that Mitek Performed Pre-Suit Testing on Coated vs. Uncoated FiberWire (D.I. 127 and D.I. 128);

(3) Mitek's Motion *In Limine* (No. 3) and Memorandum in Support to Preclude Arthrex from Relying on U.S. Patents 4,074,713 and 4,074,366 (D.I. 120 and D.I. 121);

(4) Mitek's Motion *In Limine* (No. 4) and Memorandum in Support to Limit the Testimony of Arthrex's Patent Law Expert, Mr. Witherspoon (D.I. 124 and D.I. 126);

(5) Mitek's Motion *In Limine* (No. 5) and Memorandum in Support to Preclude Arthrex and Pearsalls From Making Irrelevant and Prejudicial Remarks About Mitek (D.I. 129 and D.I. 130); and

(6) Mitek's Emergency Motion to Prevent Defendants From Presenting Witnesses at Trial Who Were Not Disclosed as Trial Witnesses During Fact or Expert Discovery (D.I. 113 and D.I. 114).

H. Mitek Requests A Ruling That These Facts Be Established As Admitted

In preparing the Pretrial Memo, the parties stipulated to a number of facts (D.I. 136 at Ex. A (also attached hereto as Ex. 1)), but could not reach agreement on the facts proposed below, many of which are simply foundational for testimony to be presented by Mitek's expert witnesses. Because of the one-week time frame for the trial, Mitek hoped to streamline evidentiary issues so that it would not need to present designated testimony on documents and facts solely for authentication and foundation purposes. Defendants, however, would not agree to the below facts despite the record support for the same (Ex. 16).

1. PX-279 is a 2001 manufacturing flow chart for TigerWire and FiberWire. Pearsalls witness, Mr. Hallett, testified about this document. Defendants have not objected to this document (D.I. 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

> FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 279 (Ex. 17 at 12:21-13:9; 13:15-19; DMI Ex. 279).

2. Pearsalls witness, Mr. Hallett, also testified about the details of the manufacturing process described in PX-279. Mitek proposed various facts relating to the manufacturing processes, but the Defendants would not agree to the facts, objecting as "irrelevant and confusing" (Ex. 16 at Stipulated Facts 49-53). Mitek advised the Defendants that because they

put FiberWire's coating in issue, the manufacturing processes for FiberWire are relevant. They disagreed. Accordingly, Mitek requests a ruling that the following facts be established for trial.

a. Pearsalls' "dye stage" testing occurs after the dying and scouring process but before the winding, stretching and coating, and final inspection/measuring processes (Ex. 18 at 47:24-48:3; DMI Ex. 279).

b. Pearsalls' "intermediate" testing occurs after the stretching and coating processes in Mitek deposition Ex. 279 but before the final inspection/measuring processes (Ex. 18 at 49:14-16; DMI Ex. 279).

c. Pearsalls' final stage measuring test occurs after the stretching and coating processes in Mitek deposition Ex. 279 and when Pearsalls' has completed manufacturing the product (Ex. 18 at 53:18-25; DMI Ex. 279).

d. There should not be any construction or manufacturing difference between FiberWire samples from the same batch that are tested at Pearsalls' intermediate and final tests (Ex. 18 at 54:1-6; DMI Ex. 279).

3. PX-281 is a 2005 manufacturing flow chart for TigerWire and FiberWire. Pearsalls witness, Mr. Hallett, testified about this document. Defendants have not objected to this document (D.I. at 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

a. FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 281 (Ex. 19 at 14:8-16; 19:10-13).

4. R.K. Manufacturing is the company to which Pearsalls sells the suture which is ultimately sold as FiberWire (*see* Ex. 20 at Stipulated Fact #7). Defendants objected to Mitek's proposed fact because the language **"'**alter the construction' is undefined, confusing and misleading " (Ex. 20 at Stipulated Fact Objection #10). Mitek disagrees since it is clear from Mr. Ponton's testimony what he was referring to in giving this testimony. Accordingly, Mitek requests a ruling that the following fact be established for trial:

RK Manufacturing does nothing to alter the construction of the braid it receives from Pearsalls and sells to Arthrex (Ex. 20 at 74:16-21).

5. PX-282 is a FiberWire sample described by Pearsalls witness, Mr. Hallett, at his deposition. Defendants have not objected to this sample (D.I. 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

> The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 282, underwent all FiberWire manufacturing processes prior to the wind to skein process and the scouring process, but no other FiberWire manufacturing processes (Ex. 21 at 33:3-34:7; 36:16-18).

6. PX-283 is a FiberWire sample described by Pearsalls witness, Mr. Hallett, at his deposition. Defendants have not objected to this sample (D.I. at 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

> The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 283, underwent the FiberWire braiding process and all FiberWire manufacturing processes that are before the braiding process, but no other FiberWire manufacturing processes (Ex. 22 at 35:10-13; DMI Ex. 279).

7. PX-342 is a FiberWire sample described by Pearsalls witness, Mr. Hallett, at his deposition. Defendants have objected to this sample as irrelevant (D.I. at 136 at Ex. D). Mitek disagrees since this is relevant to the issue of whether the coating has a material effect on FiberWire, and Mitek's expert, Dr. Brookstein, relied on this in his opinions. Accordingly, Mitek requests a ruling that this fact be established for trial:

> The FiberWire sample, denoted as DePuy Mitek Deposition Exhibit 342, under went all of the manufacturing process in DePuy Mitek Exhibit 279 before the stretching and coating processes, and once coated, stretched, and heated a single time (Ex. 23 at 349:7-13; 350:1-5; DMI Ex. 279).

8. PX-316 is a FiberWire specification. Pearsalls witness, Mr. Hallett, testified about this document. Defendants have not objected to this document (D.I. at 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

> DePuy Mitek Deposition Exhibit 316 sets forth specification tolerances for FiberWire (Ex. 24 at 237:9-11; 240:21-24).

9. PX-318 is a matrix relating to FiberWire development. Pearsalls witness, Mr. Hallett, testified about this document. Defendants have not objected t this document (D.I. at 136 at Ex. D), but would not stipulate to this fact. Accordingly, Mitek requests a ruling that this fact be established for trial:

> DePuy Mitek Deposition Exhibit 318 is a matrix for the developmental and commercial FiberWire and TigerWire products (Ex. 25 at 245:21-25; DMI Ex. 318).

I. Jury Instructions

Mitek has not addressed specific issues relating to the jury instructions because certain of them depend on the evidence presented at trial, and may be addressed at the charge conference.

J. Materials Submitted With The Pretrial Memo

There are various outstanding issues relating to the exhibit lists, witnesses lists, and deposition designations that will need to be resolved.

VI. LENGTH OF TRIAL

Mitek understands that the present infringement trial will be one week beginning on August 6, 2007. Mitek has scheduled its witnesses and accommodations based on this understanding and believes that it can be completed within this time frame. Accordingly, Mitek respectfully requests that the Court consider splitting the parties' trial presentation based on a one week schedule.

Dated: July 24, 2007

DEPUY MITEK, INC.,
By its attorneys,

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CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

TRIAL BRIEF

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date *via* the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

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Dated: July 24, 2007

/s/ Erich M. Falke
Erich M. Falke

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

JOINT PROPOSED STIPULATED FACTS

Stipulated Fact #1

Arthrex, Inc. received actual notice of U.S. Patent No. 5,134,446 on December 1, 2003 (J. Schmeiding 1/5/06 Dep. at 64:12-15).

Stipulated Fact #2

FiberWire and TigerWire are surgical sutures (FiberWire IFU)(Undisputed Mitek Fact #11; Arthrex Response to Mitek Request to Admit No. 3).

Stipulated Fact #3

RK Manufacturing has sold sterilized FiberWire and TigerWire to Arthrex, Inc. within the United States (Grieff Dep. at 37:23-38:8).

Stipulated Fact #4

Arthrex, Inc. sells FiberWire and TigerWire in the United States (ARM 3355)(Undisputed Mitek Fact #51).

Stipulated Fact #5

Pearsalls manufactures the braided products that are further processed and ultimately sold as FiberWire and TigerWire sutures (Grieff Dep. at 12:2-11; 12:18-23; 16:24-17:3; 17:9-12).

Stipulated Fact #6

Pearsalls has imported into the United States unsterilized braided products that are further processed and ultimately sold as FiberWire and TigerWire sutures (Grieff Dep. at 20:10-22).

Stipulated Fact #7

Pearsalls has sold unsterilized braided products to R.K. Manufacturing which are further processed and ultimately sold as FiberWire and TigerWire sutures and suture products (Grieff Dep. at 20:10-22).

Stipulated Fact #8

Arthrex, Inc. sells FiberWire and TigerWire sutures attached to a needle (DMI Ex. 5 at ARM 001469).

Stipulated Fact #9

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 101)(Undisputed Mitek Fact #26).

Stipulated Fact #10

Arthrex's sells the following FiberWire and TigerWire suture product codes within the United States: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (ARM 3355).

Stipulated Fact #11

FiberWire sutures and TigerWire sutures sold by Arthrex are sterilized (Arthrex Response to Mitek's Request to Admit No. 3)(DMI Ex. 3 at 13-1).

Stipulated Fact #12

The cover in FiberWire suture is constructed of ultra high molecular weight polyethylene (UHMWPE) and polyethylene terephthalate (PET) (Arthrex Response to Mitek's Request to Admit No. 9).

Stipulated Fact #13

FiberWire includes a heterogeneous braid composed of a first and second set of continuous and discrete yarns (Mukherjee Dep. at 362:1-4)(Undisputed Mitek Fact #13).

Stipulated Fact #14

FiberWire includes a set of PET yarns made up of a plurality of PET filaments (Dreyfuss Dep. at 64:14-17).

Stipulated Fact #15

Each FiberWire suture product has a set of yarns made of PET (*id*.)(Undisputed Mitek Fact #49).

Stipulated Fact #16

Each yarn of PET included in FiberWire is composed of a plurality of filaments (Mukherjee Dep. at 363:7-16)(Undisputed Mitek Fact #46).

Stipulated Fact #17

FiberWire includes a set of UHMW PE yarns made up of a plurality of UHMW PE filaments (Dreyfuss Dep. at 50:21-51:1)

Stipulated Fact #18

In FiberWire, at least one yarn of ultra high molecular weight PE is in direct intertwining contact with a PET yarn (Dreyfuss Dep. at 50:21-51:1).

Stipulated Fact #19

FiberWire includes a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction (Mukherjee Dep. at 362:5-8)(Undisputed Mitek Fact #13).

Stipulated Fact #20

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id*. at 362:1-4)(Undisputed Mitek Fact #15).

Stipulated Fact #21

The ultra high molecular weight polyethylene yarns in FiberWire and Tiger Wire are continuous and discrete (*id.*)

Stipulated Fact #22

The PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET (Dreyfuss 9/16/05 Dep. at 64:14-17)(Undisputed Mitek Fact #17).

Stipulated Fact #23

No. 2 FiberWire suture, No. 5 FiberWire, No. 0 FiberWire suture, the No. 2-0 FiberWire suture, and the 3-0 FiberWire suture are braided using the same process (Dreyfuss 9/16/05 Dep. at 38:20-24)(Undisputed Mitek Fact #23).

Stipulated Fact #24

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (DMI Ex. 318)(Undisputed Mitek Fact #47).

Stipulated Fact #25

Notwithstanding the color of the yarns, TigerWire's yarns are identical to FiberWire's yarn with the exception that one PET yarn is replaced by one nylon yarn (DMI Ex. 318)(Undisputed Mitek Fact #9).

Stipulated Fact 26

The addition of nylon to TigerWire does not materially affect the basic and novel characteristics of the invention.

Stipulated Fact #27

TigerWire is braided in the same way as FiberWire (Dreyfuss 9/16/05 at 31:24–32:2)(Undisputed Mitek Fact #10).

Stipulated Fact #28

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Brookstein Op. Expert Rpt. at ¶49; DMI Ex. 318)(Undisputed Mitek Fact #50).

Stipulated Fact #29

FiberWire size 4-0 does not have a core (*id*. at 55:21-23)(Undisputed Mitek Fact #25).

Stipulated Fact #30

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id*. at 104:17-105:9)(Undisputed Mitek Fact #24).

Stipulated Fact #31

Tevdek is a 100% braided polyester suture (Sluss Dep. at 35:17-22; *See* Grafton Dep. at 36:17-18).

Stipulated Fact #32

Mr. Grafton's idea was to add the PET and to improve the knot security of the suture (Undisputed Mitek Fact #30)(*id*. at 53:24-54:5).

Stipulated Fact #33

The FiberWire prototype suture that included PET braided with ultra-high molecular weight polyethylene had good knot security (*id*. at 54:24-55:1)(Undisputed Mitek Fact #31).

Stipulated Fact #34

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 284, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes that are before the dying process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 36:1-4; 36:19-12; DMI Ex. 279).

Stipulated Fact #35

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 285, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process (Hallett 1/11/2006 Dep. at 37:10-13; DMI Ex. 279).

Stipulated Fact 36

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 286, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process. It is the same as US 2 commercial FiberWire(Hallett 1/11/2006 Dep. at 38:17-39:6; 39:12-18;40:2-9, 12-17; 41:5-11; DMI Ex. 279).

Stipulated Fact #37

DePuy Mitek Deposition Exhibit 317 sets forth specification acceptance criteria for FiberWire (Hallett 1/12/2006 Dep. at 241:15-18).

Stipulated Fact #38

Pearsalls' batch records were generated in the normal course of Pearsalls' business (Hallett 1/12/2006 Dep. at 269:5-11).

Stipulated Fact #39

Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") is a corporation organized under the laws of the State of Massachusetts and maintains its principal place of business at 325 Paramount Drive, Raynham, Massachusetts 02767.

Stipulated Fact#40

Defendant Arthrex, Inc. ("Arthrex") is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

Stipulated Fact #41

Defendant Pearsalls, Ltd. ("Pearsalls") is a corporation organized under the laws of the United Kingdom and maintains its principal place of business at Tancred Street, Taunton, Somerset, England.

Stipulated Fact #42

Ethicon, Inc. ("Ethicon") is a corporation organized under the laws of the State of New Jersey and maintains it principal place of business at U.S. Route 22 West, P.O. Box 151, Sommerville, New Jersey 08876-0151.

Stipulated Fact #43

Arthrex sells FiberWire suture in the United States, as stand-alone suture, and also attached to needles or suture anchors.

Stipulated Fact #44

Arthrex's FiberWire suture contains a braid of ultra high molecular weight polyethylene (UHMWPE) and PET.

Stipulated Fact #45

Arthrex's FiberWire suture includes a coating of NuSil Med 2174.

Stipulated Fact #46

Arthrex's TigerWire suture contains a braid of ultra high molecular weight polyethylene (UHMWPE) , PET, and one nylon yarn.

Stipulated Fact #47

Arthrex's TigerWire suture includes a coating of NuSil Med 2174.

Stipulated Fact #48

Arthrex's FiberWire sutures are tipped.

Stipulated Fact #49

Arthrex's TigerWire sutures are tipped.

Stipulated Fact #50

DePuy Mitek and Ethicon, Inc. are affiliated with Johnson & Johnson.

Stipulated Fact #51:

Before Dr. Gitis conducted the tests described in his report dated March 23, 2006, Dr. Gitis sent, via Fedex, two envelopes containing U.S. No. 2 FiberWire suture to Sterile Systems, in Grand Rapids, Michigan. One of the envelopes Dr. Gitis sent to Sterile Systems contained a plastic bag of suture and was labeled "coated." The other envelope Dr. Gitis sent to Sterile

Systems contained a plastic bag of suture and was labeled “uncoated.” The sutures were sterilized in the envelopes at Sterile Systems. The two envelopes of suture were then returned to Dr. Gitis at CETR.

EXHIBIT 2

1 of 7 DOCUMENTS

MPT, Inc., Plaintiff, Vs. Marathon Labels, Inc., and Polymeric Converting, LLC, Defendants.

CASE NO. 1:04-cv-2357

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION

2007 U.S. Dist. LEXIS 3992

January 19, 2007, Decided

PRIOR HISTORY: *MPT, Inc. v. Marathon Labels, Inc, 2006 U.S. Dist. LEXIS 47941 (N.D. Ohio, July 14, 2006)*

COUNSEL: [*1] For MPT, Inc., Plaintiff: Kyle B. Fleming, Thomas H. Shunk, LEAD ATTORNEYS, David E. Kitchen, John Edward Sullivan, Baker & Hostetler, Cleveland, OH.

For Marathon Labels, Inc., Defendant: Bruce H. Wilson, LEAD ATTORNEY, Akron, OH; Mark E. Miller, Miller & Associates, Evansville, IN.

For The Kennedy Group, Incorporated, Respondent: Thomas H. Shunk, LEAD ATTORNEY, Baker & Hostetler, Cleveland, OH.

For Marathon Labels, Inc., Counter-Claimant: Bruce H. Wilson, LEAD ATTORNEY, Akron, OH; Mark E. Miller, Miller & Associates, Evansville, IN; Richard M. Klein, Fay, Sharpe, Fagan, Minnich & McKee, Cleveland, OH.

For MPT, Inc., Counter-Defendant: Thomas H. Shunk, LEAD ATTORNEY, David E. Kitchen, John Edward Sullivan, Kyle B. Fleming, Baker & Hostetler, Cleveland, OH.

For Marathon Durable Labeling Systems LLC, Counter-Claimant: Bruce H. Wilson, LEAD ATTORNEY, Akron, OH.

For Polymeric Converting LLC, Sunbelt Consulting Group, Inc., Counter-Claimants: Richard M. Klein, LEAD ATTORNEY, Christopher B. Fagan, Fay, Sharpe, Fagan, Minnich & McKee, Cleveland, OH; James V. Costigan, John F. Volpe, Kathleen A. Costigan, Hedman & Costigan, New York, NY.

JUDGES: Patricia A. Gaughan, [*2] United States District Judge.

OPINION BY: Patricia A. Gaughan

OPINION

Memorandum Opinion and Order

INTRODUCTION

A number of post-trial motions have been filed by the parties. Plaintiff MPT, Inc. ("MPT") has filed a Motion for Entry of Judgment Including Permanent Injunction (Doc. 272) and a Motion for Attorneys' Fees (Doc. 271). Defendants Marathon Labels, Inc. ("Marathon") and Polymeric Converting LLC ("Polymeric") have filed Renewed Motions for Judgment as a Matter of Law (Doc. 270, 273). MPT has filed a Motion to Strike Defendants' Motions (Doc. 277). These motions follow a jury verdict in favor of MPT on its claims that Defendants willfully infringed *United States Patent No. 5,417,790* (issued May 23, 1995) (the "*'790 patent*") and United States Patent No. RE 37,164 E (issued May 8, 2001) (the "'164 patent"). For the following reasons, the Court GRANTS in Part MPT's Motion for Entry of Judgment Including Permanent Injunction, GRANTS in Part MPT's Motion to Strike, GRANTS in Part Defendants' Motions for Judgment as a Matter of Law and DENIES MPT's Motion for Attorneys' Fees.

BACKGROUND

MPT holds the *'790* and '164 patents, which generally claim a method for [*3] the labeling and relabeling of reusable containers. MPT sued Defendants for contributory and induced infringement on Claims 1, 2, 3, 4 and 6 of the *'790 patent* and Claim 1 of the '164 patent. MPT claims that Marathon's customers infringe MPT's

patents when they use Marathon's Smart Surface Placard product. Polymeric manufactures the Teflon surface of the Smart Surface Placard. Following a two-week jury trial a unanimous jury returned a verdict that both Defendants had contributed to the infringement of all of the patent claims at issue, that Marathon had induced infringement of all of the patent claims at issue, and that the infringement was willful. (Doc. 267, 269). Plaintiff now seeks entry of judgment, trebled damages, a permanent injunction and attorneys fees. Defendants oppose MPT's motions in part by reference to the arguments set forth in their renewed motions for judgment as a matter of law.

DEFENDANTS' *RULE 50(B)* MOTIONS

a. Standard of Review - *Rule 50*

Defendants have filed renewed motions for judgment as a matter of law under *Rule 50(b)*. The Court of Appeals for the Federal Circuit generally decides *Rule 50(b)* issues under regional circuit law, since [*4] "JMOL is not a patent-law-specific issue . . . ." *Harris Corp. v. Ericsson Inc., 417 F.3d 1241, 1248 (Fed. Cir. 2005)*. "Judgment as a matter of law is appropriate when 'viewing the evidence in the light most favorable to the non-moving party, there is no genuine issue of material fact for the jury, and reasonable minds could come to but one conclusion, in favor of the moving party.'" *Jordan v. City of Cleveland, 464 F.3d 584, 594 (6th Cir. 2006)* (quoting *Noble v. Brinker Int'l, 391 F.3d 715, 720 (6th Cir. 2004)*); *see also Power-Tek Solutions Services, LLC v. Techlink, Inc., 403 F.3d 353, 358-59 (6th Cir. 2005)* (explaining that the verdict must be supported by "substantial evidence" and the motion should be granted "[o]nly when it is clear that reasonable people could come to but one conclusion"). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge." *Jordan, 464 F.3d at 594* (quoting *Reeves v. Sanderson Plumbing Prods., 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000))*.

MPT's motion to strike focuses [*5] on waiver of the right to file a post-trial JMOL motion. A party can waive its right to file a *Rule 50(b)* motion where the *Rule 50(a)* motions made at trial failed to "specify the judgment sought and the law and facts on which the moving party is entitled to judgment." *Fed. R. Civ. P. 50(a)(2)*. Although JMOL issues are generally governed by regional circuit law, Federal Circuit law governs whether general arguments made in a pre-verdict JMOL motion are sufficient to preserve specific patent law issues for a post-verdict JMOL motion. *Duro-Last, Inc. v. Custom Seal, Inc., 321 F.3d 1098, 1106 (Fed. Cir. 2003)*. The two standards are not appreciably different in any event. Both Circuits recognize the Rule's purpose to alert the non-moving party and the court to the grounds of the motion prior to the submission of the case to the jury. *See Jordan, 464 F.3d at 595* (noting that the pre-verdict motion must state the grounds with sufficient certainty that the court and opposing counsel are aware of the movant's position); *Duro-Last, 321 F.3d at 1107* (explaining that "it would be constitutionally impermissible [*6] for the district court to re-examine the jury's verdict and to enter JMOL on grounds not raised in the pre-verdict JMOL").

b. Infringement

1. Failure to Comply with *Rule 50(a)(2)*

MPT argues in its Motion to Strike that Defendants have raised new noninfringement arguments in their renewed motions. The Court has reviewed the various motions and agrees that a number of noninfringement arguments in the *Rule 50(b)* motions were not stated in the pre-verdict motions: 1) MPT failed to prove that the direct infringers utilize "reusable" containers; 2) MPT provided no evidence that any Marathon customer placed and removed pressure sensitive adhesive labels on Marathon's product; 3) MPT failed to provide any evidence that a "first product," "first contents set," "another product" or a "second contents set" is placed in a reusable container; 4) MPT failed to prove that the labels included "product quantities," "indicia" or product "information"; 5) MPT failed to prove that a first product set was positioned "at a selected one of a time prior to and subsequent to the first label applying step"; and 6) MPT failed to prove infringement of Claims 2 and 3 of the *'790 patents* with respect [*7] to the printing and transparent surfaces.

Defendants point to excerpts of the trial transcript as supporting their post-verdict motions. However, the best that can be said for these excerpts and related written materials is that Defendants stated in the most general terms that MPT had failed to prove that all elements of the method claims were infringed. This characterization may be somewhat charitable, since most mentions of claim elements other than a "release coated," "placard" or "substantially permanent attachment" related to whether the method steps were performed in the United States, not whether they were performed at all. It is also notable that these subjects were not part of Defendants' trial brief, closing arguments, or trial strategy. The Court must therefore decide whether a general statement in a pre-verdict JMOL motion that the plaintiff has failed to prove that all elements of the claims were practiced by Defendants preserves the right to challenge specific elements (or dependent claims with respect to claims 2 and 3) that were never mentioned in the pre-verdict motion.

The Federal Circuit recently addressed a similar issue in *Duro-Last.* The *Duro-Last* defendant [*8] moved

for pre-verdict JMOL on inequitable conduct and the on-sale bar but failed to explicitly move on obviousness. *321 F.3d at 1106*. The defendant noted in its post-verdict motion on obviousness that the inequitable conduct motion discussed prior art references that were also relevant to obviousness. *Id. at 1107*. The Federal Circuit held that this was not adequate to preserve the issue for a *Rule 50(b)* motion. New prior art references were raised in the post-verdict motion and the pre-verdict motion lacked any discussion of the previously-disclosed prior art references with respect to obviousness factors. [1] *Id.*

1 The Federal Circuit also concluded that a pre-verdict JMOL on the on-sale bar was not sufficient to support a post-verdict motion on obviousness. *Duro-Last, 321 F.3d at 1107*.

This case is quite similar to *Duro-Last.* Just as the *Duro-Last* plaintiff was unable to address the new prior art, MPT never had an opportunity at trial to address [*9] Defendants' new noninfringement arguments. *See also W.S. Molnar Co. v. IKG Indus., 1996 U.S. App. LEXIS 6311, 39 U.S.P.Q.2d (BNA) 1219 (Fed. Cir. 1996)* ("A general reference to a count . . . is insufficient to meet the rule's requirements" (citing *Libbey-Owens-Ford Co. v Inc. of N. Am., 9 F. 3d 422, 426 (6th Cir, 1993))*. Other district courts have reached a similar conclusion in patent cases. *See, e.g., Am. Standard, Inc. v. York Int'l Corp., 244 F. Supp. 2d 990, 993 (W.D. Wisc. 2002)* (allowing a post-verdict motion to elaborate upon the pre-verdict anticipation argument but not to set forth arguments on a new claim element). The Court's conclusion is buttressed by the fact that the new arguments could not even be gleaned from Defendants' conduct or argument at trial. [2]

2

Courts usually "take a liberal view of what constitutes a pre-verdict motion sufficient to support a post-verdict motion" where the purpose of the rule--alerting the nonmovant and the Court of deficiencies in the nonmovant's case--is met. *Kusens v. Pascal Co., 448 F.3d 349, 361 (6th Cir. 2006)*. This explains cases like *Malta v. Schulmerich Carillons, Inc.*, which affirmed a post-verdict grant of JNOV where the attorney merely "moved for a directed verdict on claim 2 and claim 3 of the 082 patent on the grounds that the evidence is insufficient." *952 F.2d 1320, 1324-25 (Fed. Cir. 1991)*. The post-verdict argument in *Malta* was related to the main infringement issue in the proceedings, not to new arguments that were never even addressed by Defendants as occurred in this case. In another case cited by Defendants, the Federal Circuit considered the motion because the moving party was cut short by the Court in its pre-verdict motion. *Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 683 (Fed. Cir. 1990)*.

[*10] Accordingly, the Court concludes that Defendants have waived certain noninfringement grounds which were never raised during pre-verdict JMOL motions. The Court will not consider any of the six arguments listed above. [3]

3 Many of the new arguments (e.g., regarding products sets and pressure sensitive labels) are conclusory and belied by clear trial testimony. Other new arguments that are given substantial attention by Defendants are completely frivolous. For example, Defendants argue that testimony regarding "returnable" containers failed to prove that "reusable" containers were used by direct infringers. However, witnesses testified in detail that the "returnable" containers were in fact "reused" many times over. Defendants also argue that the claim language "at a selected one of a time prior to and a time subsequent to the first label applying step positioning a first product set on the object" means that two first product sets must be positioned on the object--one at "a time prior to" and a second at "a time subsequent to" the first label applying step. This argument flatly ignores that the first product set is positioned "at a selected one of" these two times.

[*11] 2. Testimony of Dr. Prahl

Defendants generally ask the Court to disregard the testimony of MPT's expert, Dr. Prahl. The Court rejects these arguments for the same reasons it did at trial. As a threshold matter, Defendants did not object to Dr. Prahl's testimony in a timely manner. Moreover, even if they had objected properly the Court finds that Prahl's testimony was proper and that Defendants' objections merely go to weight to be given his testimony.

3. Substantially Permanently

Defendants argue that MPT failed to demonstrate that Marathon's customers "substantially permanently" attach the Smart Surface Placard to containers. First, they note that Richard Rizzi, the representative of a Marathon customer, testified that a specimen demonstrated to the jury was a poor example because it was placed over the residue of a previous placard rather than directly on the surface of the container. They also attack a video demonstration performed by Patrick Kennedy. They claim that "no direct evidence was offered as to: 1) when the testing was actually begun; 2) by what method the Smart Surface Placard was attached to the container; 3) where the container was obtained; 4) what type [*12] of container was utilized; 5) what the condition was of the container

prior to testing; 6) what conditions the container was subjected to from the time the Marathon Smart Surface Placard was attached to the container until it was removed; or 7) why the Marathon Smart Surface Placard was removed from the container and taken out of view during the video taping." They argue further that MPT failed to explain a connection between the container used in the demonstration and the containers used by Marathon customers. Finally, Defendants note that MPT has certain product tests performed by independent companies while the videotaped test was performed by Patrick Kennedy. From these observations they conclude that "Plaintiff's demonstrations are haphazard at best and are, therefore, entitled to no evidentiary weight" and that Plaintiff failed to meet its burden of proving literal infringement.

MPT responds that the jury was shown ample evidence that the Marathon placards substantially permanently attach to objects or containers. With respect to the testimony of Rizzi, the Marathon placards are sometimes placed over existing, damaged placards in their end use. With respect to the Kennedy demonstration, [*13] Patrick Kennedy did in fact testify as to the timing of the tests, the choice of substrates for testing, and the method used to adhere the Marathon placards. The jury could observe the conditions under which the test was performed. As for Kennedy's potential bias, the jury was well aware of his position with MPT.

MPT also points to Defendants' own tests. It notes that the jury could have concluded that the videotaped test Defendants demonstrated to the jury actually proved substantially permanent attachment. First, the test shown to the jury could reasonably demonstrate damage to the placards as required by the Court's claim construction. Second, the video demonstrator testified that he performed a first test in which he could not remove the Marathon placards from the container using his fingers. This test was recorded over by the demonstrator and could not be shown to the jury.

Finally, the jury was also provided with testimony regarding the Marathon adhesive, the strength with which it adheres to various substrates, and its classification as a permanent adhesive.

The Court concludes that reasonable jurors could find that the Smart Surface Placard substantially permanently attaches [*14] to the containers used to practice the method. Defendants' arguments go to the weight to be given the Rizzi and Kennedy demonstrations, and were fair game for argument before the jury. A jury could also reasonably observe that the Smart Surface Placards were substantially permanently attached in Defendants' own demonstration, particularly in light of the first test which was performed and then recorded over. [4] Finally, the evidence regarding the adhesive provided further support that the placards are substantially permanently attached by end users.

4 Defendants note that the videographer testified that he could not remove the labels in the first test because he had short fingernails. However, this is just the sort of credibility determination that juries are supposed to resolve.

4. Release Coated - Placard

Defendants contend that the Court erred in ruling at trial that no reasonable juror could find that Marathon's Smart Surface Placard did not have the claim elements of a "placard" with a "release [*15] coated" face. They claim that the undisputed evidence demonstrates that the placard has two adhesive coated faces and thus cannot have a release coating. In this regard, the structure of the Marathon product was undisputed. At the center of the product are two attached polyester layers. The exterior surface of the first polyester layer has adhesive that is used to attach to containers. The exterior surface of the second polyester surface has a layer of adhesive that attaches the Teflon release surface.

The Court defined a "release coating" as "a covering that permits the easy and complete removal of pressure sensitive adhesive labels" and a "placard" as "a structure adapted for supporting a pressure sensitive adhesive backed label." The patents generally claim a "placard having a release coated face . . . ." Defendants argued in opposition to MPT's summary judgment motion on infringement that the adhesive layer between the second polyester layer and the Teflon release surface precluded a finding that the placard had a release coated face. The Court denied MPT's motion for summary judgment because MPT failed to provide any evidence as to the character of the adhesive that attached [*16] the Teflon release surface.

At trial MPT presented conclusive evidence and legal argument such that no reasonable juror could find that the placard lacked a release coated surface. With respect to the evidence, the adhesive is a thin layer with the sole purpose of attaching the Teflon to the polyester surface. Even if the polyester surface is the "face" of the placard, the Teflon still "covers" that face as required by the claims, since the Teflon can cover the placard even if it is not in direct contact with the placard. MPT also presented a correct legal argument that the claim term "placard" includes the adhesive layer, since the adhesive used to attach the Teflon is part of "a structure adapted for supporting a pressure sensitive adhesive backed label." Since the adhesive used to attach the Teflon is the exterior face of the placard, the Teflon is in direct contact with and thus covers the placard face.

The Court therefore concludes that its decision at trial was proper.

5. All Elements Rule - in the United States

Defendants also argue that MPT failed to prove that any Marathon customer performed all steps of the method in the United States. As the Court noted at trial, [*17] to prove infringement of the method claims MPT was required to prove that all steps of the method were performed by a customer in the United States. *See NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282, 1318 (Fed. Cir. 2005)*. The Court agrees with MPT that the jury reasonably concluded that MPT did prove all steps of the method were performed in the United States. Marathon flatly admitted that at least some of its customers perform all of the steps of the method in the United States. Marathon's largest customer also testified to all of the steps of the method being performed in the United States. Although in some cases certain method steps are performed in Mexico, the jury clearly considered this and limited damages accordingly.

6. Contributory Infringement - Substantial Non-Infringing Use

In this case, it was Marathon's customers who practiced the method. Marathon and Polymeric were accused of contributory infringement and inducement to infringe. Contributory infringement requires that the items sold by Marathon and Polymeric are "not a staple article or commodity of commerce suitable for substantial noninfringing use." *35 U.S.C. 271(c)* [*18] .

Defendants make two arguments with respect to substantial non-infringing uses. First, they generally argue that MPT failed to show that the products produced by Defendants do not have other uses. However, Marathon testified that the Smart Surface Placards are "all custom products." Testimony from Polymeric indicated that the Teflon coating was produced specifically for Marathon's application. MPT's expert also testified that the sole purpose of Marathon's end-product was to perform the patented method. Based on this testimony, a jury could reasonably conclude that MPT met its burden of demonstrating no substantial noninfringing use. [5]

5 Defendants also argue that use of the Smart Surface placard on racks is a substantial noninfringing use. The jury implicitly found that sales for racks are not a substantial noninfringing use. This conclusion was reasonable in light of Claim 6 of the *'790 patent*, which covers a "process for providing product information on *objects* . . . ." (emphasis added). It is clear from Claim 7 that object is broad enough to include racks, since that dependent claim further provides for "the process of claim 6 wherein the object is a container." *See Kim v. ConAgra Foods, Inc., 465 F.3d 1312, 1319 (Fed. Cir. 2006)* ("The doctrine of claim differentiation suggests that the independent claims here should not include explicit limitations of a dependent claim.").

[*19] Defendants' second argument is a legal argument that the use of their products to perform the methods abroad is a substantial noninfringing use. The Court agrees with other courts to address the issue that the substantial noninfringing use cannot be acts that would otherwise infringe but are performed in a country where there is no patent. [6] *Lucas Aerospace, Ltd. v. Unison Indus., L.P., 899 F. Supp. 1268, 1287 (D. Del. 1995)*; *02 Micro Int'l Ltd. v. Sumida Corp., No. 2:03-cv-07, 2006 U.S. Dist. LEXIS 18859, *8 (D. Tex. 2006)*; *LG Elecs., Inc. v. Asustek Computer, Inc., No. C 01-00326, 2002 U.S. Dist. LEXIS 25956, *35-37 (N.D. Cal. Aug. 20, 2002)*. As a general rule, United States patent laws do not reach conduct that occurs overseas. *Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531, 92 S. Ct. 1700, 32 L. Ed. 2d 273 (1972)* (explaining that "[o]ur patent system makes no claim to extraterritorial effect"). It follows that acts that occur overseas cannot serve as a substantial noninfringing use for purposes of a domestic infringement analysis. This is particularly true where the overseas use would be an infringement of the patent if it occurred [*20] in the United States. The peculiar result of Defendants' reasoning would be that contributory infringers are immune from liability so long as the component used to infringe the method is also exported elsewhere. Defendants' reasoning might also require courts to opine on the scope of foreign patent rights. For example, if the patentee has a patent in a foreign country, the infringement of that foreign patent would negate a finding of a substantial noninfringing use. The Court does not believe Congress envisioned a test that would require advisory rulings on foreign patent rights as a precursor to liability in this country. For these reasons, the Court rejects Defendants' argument.

6 Defendants argue that none of these other courts have addressed a method patent. However, *Section 271(c)* does not distinguish between components that can be used to practice a method and components that can be combined into an apparatus. The Court cannot see any reason to distinguish between the two on the issue of whether foreign activities can serve as a substantial noninfringing use.

[*21] 7. Contributory Infringement - Polymeric

Polymeric argues that it cannot be liable in light of the Court's jury instruction regarding contributory infringement. The Court adopted MPT's proposed instruction and instructed the jury as follows:

MPT argues that Marathon and Polymeric have contributed to infringement by another. Contributory infringement may arise when someone supplies something that is used to infringe one or more of the patent claims. In order for there to be contributory infringement by a defendant, someone other than that defendant must directly infringe a claim of the *790* or 164 patents; if there is no direct infringement by anyone, there can be no contributory infringement. If you find someone has directly infringed the *790* or 164 patent, then contributory infringement exists if:

(1) The defendant supplied an important component of the infringing part of the method;

(2) The component is not a staple article of commerce suitable for non-infringing use; and

(3) The defendant supplied the component with the knowledge of the *790* and 164 patent and knowledge that the component was especially made or adapted for use in an infringing manner.

A "staple article [*22] of commerce capable of substantial noninfringing use" is something that has uses other than in the patented method, and those other uses are not occasional, farfetched, impractical, experimental, or hypothetical. In this case, as I have explained, MPT argues that Marathon's customers and others who use the product are the ones who are directly infringing the patents, and that the 'important component' supplied to them is the Smart Surface TM Placard. Defendants argue that the way the customers and others who use the Smart Surface TM Placard use that product does not infringe any claim of the *790* or 164 patents.

If you find that Marathon and/or Polymeric has contributed to the infringement of at least one claim of the *790* or 164 by another, then they are responsible for infringing that claim as if they were direct infringers.

Polymeric notes that the jury instruction states that "the 'important component' supplied to [Marathon's customers] is the Smart Surface TM Placard." Polymeric argues that this portion of the instruction required the jury to find that Polymeric actually supplied the Smart Surface placard in order to find it liable for contributory infringement. It points [*23] to testimony that its role was to provide the Teflon laminate to Marathon, which then combined the Teflon with other components [7] to make and sell the Smart Surface product. Marathon was thus the only Defendant to supply the finished Smart Surface product to its customers.

> 7 Polymeric notes in passing that its "role in producing the Teflon laminate is analogous to Avery Dennison's role in supplying a laminate that Marathon utilized in the manufacture of Marathon's Smart Surface Placard." Although there are some parallels, the Court notes a major distinction that the Avery Dennison portion of the Smart Surface placard is a standard product with obvious substantial noninfringing uses.

The Court finds that the jury instruction did not limit the jury as Polymeric contends. The portion of the instruction referenced by Polymeric merely described one portion of the component/supply relationship--i.e., the important component supplied by Marathon to its customers. Although it would have been acceptable to further [*24] explain that the important component supplied by Polymeric to Marathon [8] was the Teflon laminate, the instruction as a whole is clear that each Defendant, and the component supplied by that Defendant, must be considered individually.

> 8 The jury could also reasonably conclude from testimony, correspondence and Polymeric's own patent that Polymeric knew that the product it supplied to Marathon would be used to produce a product to practice the patented method.

8. Inducement to Infringe

Marathon's only argument is that MPT failed to prove direct infringement. Because the Court disagrees, the Court also finds that the inducement verdict is supported by substantial evidence.

c. Invalidity/Unenforceability

1. Failure to Comply with *Rule 50(a)(2)*

MPT also challenges Defendants' original JMOL motions on invalidity. It points to the argument of defense counsel at the close of the rebuttal case. However, that argument also incorporated earlier arguments, including Defendants' arguments in opposition [*25] to Plaintiff's JMOL motion at the close of Defendants' case

on invalidity, unenforceability and noninfringement. Referring back to that portion of the transcript, Defendants fully addressed the issues of obviousness, written description, indefiniteness and unenforceability. On these issues MPT was fully apprised of Defendants' position and the purpose of the rule has been met. *Kusens, 448 F.3d at 361*; *Jordan, 464 F.3d at 595*.

2. Obviousness

Defendants first state that the Court erred in submitting obviousness to the jury. The Court disagrees:

> Obviousness is a question of law based on factual underpinnings. *Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)*. When the parties dispute the underlying facts, the issue of obviousness typically is submitted to the jury, as it was in this case. *See Jurgens v. McKasy, 927 F.2d 1552, 1557, 18 USPQ2d 1031, 1035 (Fed. Cir. 1991)*.

Duro-Last, 321 F.3d at 1108; *see also Hewlett-Packard Co. v. Mustek Sys., 340 F.3d 1314, 1319 (Fed. Cir. 2003)*.

With respect to the jury's decision, [*26] Defendants did not claim that a single reference anticipated MPT's claims. Rather, they argued that a combination of prior art rendered the invention obvious. Obviousness is tested under the following standard:

> One attacking the validity of a patent must present clear and convincing evidence establishing facts that lead to the legal conclusion of invalidity. *35 U.S.C. § 282*. To establish invalidity under *35 U.S.C. § 103*, certain factual predicates are required before the legal conclusion of obviousness or nonobviousness can be reached. The underlying factual determinations to be made are (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, such as commercial success, long-felt but unsolved need, failure of others, copying, and unexpected results. *Graham v. John Deere Co., 383 U.S. 1, 17, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)*.

Apple Computer, Inc. v. Articulate Sys., Inc., 234 F.3d 14, 26 (Fed. Cir. 2000).

Defendants [*27] claim that the patented method was rendered obvious by the combination of a number of prior art references. French Patent No. 2 649 522 and Derwent Publications Alerting Abstract Bulletin Week 9109 of French Patent No. 2 649 522 describe a structure with a silicone release surface for the labeling and relabeling of computer diskettes. Defendants' expert Stempel testified that this is essentially what MPT's patents attempt to claim. IRS address labels and other piggyback labels were in common use and also had a release surface that allowed for the removal of pressure sensitive adhesive labels. Testimony from an industry representative and an industry handbook explained that a piggyback label could be used for multiple applications of labels. As for the concept of labeling and relabeling, Robert Petrou, the inventor of the patents-in-suit, testified that he came up with his idea while observing Goodyear labeling and relabeling its containers, albeit without the use of a placard and with a buildup of residue. Delphi representative Rizzi testified that it had been labeling and relabeling for many years without the use of a placard. From this evidence Defendants conclude that the structure [*28] used to practice the method was not novel, that labeling and relabeling was not novel, and that the use of the structure to label and relabel was obvious.

Plaintiff responds, and the Court agrees, that Defendants are not entitled to JMOL on obviousness. A reasonable jury could conclude that the scope and content of the prior art was substantially different from the method and underlying structure of MPT's patents. MPT's expert Prahl testified to a number of structural differences between the device of the French patent and the structure used to practice MPT's patented method. The actual use of piggyback labels was as a carrier for a pressure sensitive adhesive label. In the example of an IRS 1040 label, the label is reused while the placard portion is thrown away. This is the opposite of MPT's method, where the placard is reused many times over. Testimony regarding prior practice of the method without a release coated placard actually supports a finding of nonobviousness. Prior to MPT's invention Goodyear and Delphi had difficulty removing labels and applying new ones, but nonetheless failed to utilize a placard to perform labeling and relabeling. A jury could reasonably conclude [*29] that those skilled in the art, such as Goodyear, Delphi and their suppliers, therefore did not find it obvious to use a placard to perform the method. Finally, the jury received evidence of substantial commercial success under the patent, industry awards, and copying by others--all of which are relevant objective evidence of nonobviousness.

3. Written Description

The Court previously summarized the written description requirement as follows:

> As applied to this case, this means that the language of the later-amended claims must find appropriate support in the original specification of the '882 application. That specification must include sufficient information to show that the inventor possessed the later-claimed invention at the time of the original disclosure. *Pandrol USA, LP v. Airboss Railway Prods., Inc., 424 F.3d 1161, 1165 (Fed. Cir. 2005)*. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. [*30] '" *Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003)* (quoting *Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991))*.
>
> Although generally stated as the "possession" test, a showing of actual possession at the time of the original disclosure is not enough; rather, "the written description requirement is satisfied by the patentee's disclosure of 'such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.'" *Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 969 (Fed. Cir. 2002)* (quoting *Lockwood v. American Airlines, 107 F.3d 1565, 1572 (Fed. Cir. 1997))*. In other words, the purpose of the test is to demonstrate possession of the claimed invention and possession is proved by full disclosure of what is claimed. *Enzo, 323 F.3d at 969*. "The possession test requires assessment from the viewpoint of one of skill in the art." *Pandrol, 424 F.3d at 1165*.

(Doc. 168).

As the Court previously explained in denying Defendants' motion for summary judgment that "substantially permanently" [*31] fails the written description test, that exact phrase does not appear in the original specification. Nonetheless, the original specification describes firmly securing the placard to a container using an adhesive, which closely parallels "substantially permanently" attaching a placard to a container with an adhesive as is described in the claims. The specification also describes permanent adhesives with respect to labels, which are known in the art to be the same type of adhesives used on the placard portion. There was a great deal of testimony at trial regarding the known properties of adhesives and adhesive bonding from which the jury could come to understand the level of skill in the art and reasonably conclude that Defendants failed to meet their burden of proving that MPT did not possess or describe the concept of "substantially permanent" attachment at the time the specification was filed.

4. Indefiniteness

The indefiniteness inquiry originates from the statutory requirement that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *35 U.S.C. § 112* [*32] P2. A claim is invalid as indefinite if it is not amenable to construction. *Aero Prods. Int'l, Inc. v. Intex Rec. Corp., 466 F.3d 1000, 1016 (Fed. Cir. 2006)*. At the behest of Defendants, the Court construed "permanently" by reference to a common industry definition of a permanent adhesive. Defendants now argue that other definitions of permanently--such as "high adhesion," "great deal of force to remove," and "high ultimate adhesion to a wide variety of surfaces"--render it impossible to construe permanently. To the contrary, these definitions are all similar, and only serve to reinforce that permanently is a term that was amenable to construction and was properly defined in the first place.

Defendants also argue that the claims are indefinite because adhesives have different properties on different substrates. This argument misses the point of the claims. They do not claim a particular adhesive or a substrate, but rather a method involving "substantially permanently" attaching a placard to a substrate. If a potential infringer chooses a substrate and adhesive where the placard does not attach in this manner, there is no infringement. The patent claims here provide [*33] ample guidance for competitors to make such an assessment.

5. Inequitable Conduct

A patent applicant has a duty of candor and good faith before the Patent and Trademark Office. *37 C.F.R. § 1.56(a)*. Courts enforce the duty of candor and good faith through the doctrine of inequitable conduct. *Molins PLC v. Textron, 48 F.3d 1172, 1178 (Fed. Cir. 1995)*. Inequitable conduct includes affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. *Li Second Family Ltd.*

P'shp. v. Toshiba Corp., 231 F.3d 1373, 1378 (Fed. Cir. 2000). When a claim of inequitable conduct is based on an applicant's failure to disclose material information, the party challenging the patent must show that the prior art information was material to patentability, the applicant had knowledge of the prior art and of its materiality, and the applicant intended to mislead the PTO through the failure to disclose the information. *FMC v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987)*.

The jury concluded that Defendants failed to meet [*34] their burden of proving inequitable conduct. Defendants challenge that conclusion. However, the Court finds that the jury could have reasonably concluded that the applicant did not fail to disclose anything. There was conflicting testimony whether the applicant submitted an actual IRS label or a photocopy. If an actual label was submitted the jury could easily find that the duty of candor was satisfied.

d. Damages

Defendants do not seriously challenge the amount of damages. Indeed, the jury only awarded $ 3,561.64 in damages based on a 7% reasonable royalty rate. In light of the total sales of products used to perform the patented method, this verdict clearly accounted for noninfringing sales, such as those to customers in Mexico. *See State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1072 (Fed. Cir. 2003)* ("A jury's decision with respect to an award of damages 'must be upheld unless the amount is "grossly excessive or monstrous", clearly not supported by the evidence, or based only on speculation or guesswork.'")(citation omitted).

Defendants focus instead on the jury's finding that infringement was willful. [9] A potential infringer [*35] on notice of another's patent right has an affirmative duty of due care to avoid infringement. *Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1109 (Fed. Cir. 1986)*. "A finding of willfulness requires that the fact-finder find, by clear and convincing evidence, that the infringer acted in disregard of the infringed patent with no reasonable basis to believe it had a right to do the acts in question." *Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1279 (Fed. Cir. 1995)*; *State Contracting & Eng'g Corp. v. Condotte Am., Inc., 346 F.3d 1057, 1063 (Fed. Cir. 2003)*. "This is a factual determination made after considering the totality of the circumstances." *Transmatic, 53 F.3d at 1279*. "[T]he primary consideration is whether the infringer, acting in good faith and upon due inquiry, had sound reason to believe that it had the right to act in the manner that was found to be infringing." *SRI Int'l v. Advanced Tech. Lab., 127 F.3d 1462, 1464-65 (Fed Cir. 1997)*. Factors to be considered include "[w]hether the infringer intentionally copied the ideas of another; whether the infringer, [*36] once on notice of the patented invention, investigated the scope of the patent to form a good-faith belief that it was invalid or not infringed; and the infringer's behavior as a party to the litigation . . . ." *In re Hayes Microcomputer Prods, 982 F.2d 1527, 1543 (Fed Cir. 1992)*.

9 The Court finds that Defendants adequately raised the issue of willfulness in their motions at trial.

The Court agrees with Defendants that a reasonable jury could not conclude that MPT submitted clear and convincing evidence of willful infringement. Rather, all of the evidence and testimony points to a conclusion that Defendants' infringement was not willful. When Marathon's Hurley came across a product which he believed to infringe earlier in his career, he immediately removed the product from the market. These are the acts of a person acting in good faith to avoid infringement. Although MPT accuses Defendants of slavishly copying their product, the undisputed testimony is that the products themselves have [*37] a different structure. They are manufactured from different sublaminates. Although this ultimately did not result in a verdict of noninfringement, [10] the undisputed testimony is that Defendants attempted to design around Plaintiff's patent. Infringement is not willful simply because Plaintiff's product was the starting point for Defendants' product. [11] *Read Corp. v. Portec, Inc., 970 F.2d 816, 828 (Fed. Cir. 1992)*. Rather, the patent system encourages good faith attempts to "design around" patented inventions. *Id.; see also WMS Gaming Inc. v. Int'l Game Tech., 184 F.3d 1339, 1355 (Fed Cir. 1999)* ("When the district court reconsiders its finding of willful infringement, it should bear in mind that the patent law encourages competitors to design around existing patents"). The fact that the Defendants' design turned out to be within the scope of the patent is not conclusive; what matters is state of mind. *Read, 970 F.2d at 828*.

10 For example, the structure of the "placard" portion of the two products is substantially different. However, a "placard" was widely defined as a "a structure adapted for supporting a pressure sensitive adhesive backed label." Similarly, the "release coating" of the Marathon product is made from Teflon while MPT's product is made from silicone. Both are nonetheless "coverings that permits the easy and complete removal of pressure sensitive adhesive labels."

[*38]

11 The Court of course recognizes that these are method patents at issue. However, the method involves the use of a specific structure. One way to avoid infringement would be to design a product that does not have that structure but can perform the same method steps.

Plaintiff argues that Defendants should have obtained an opinion of counsel. However, the Federal Circuit recently explained that the failure to obtain legal advice does not result in an adverse inference with respect to willful infringement. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp., 383 F.3d 1337, 1345 (Fed. Cir. 2004)*; *see also State Contracting, 346 F.3d at 1064* (noting that "we have not held that obtaining the advice of counsel is the only means to avoid a finding of willfulness, regardless of the circumstances"). Here, Dronzek of Polymeric--a person with significant industry experience--testified to his good faith belief that the Teflon surface he produced for use with the Smart Surface Placard was not a "release coating" as contemplated by the claims. [12] Along those [*39] lines, he obtained a patent related to the Smart Surface Placard. [13] Marathon's Smart Surface Placard was not sold until after the patent issued. In light of these circumstances, the only reasonable conclusion is that Defendants took care not to infringe.

12

Dronzek relied in part on a statement from a later Kennedy patent application that "The release surface may be a coating applied to the protective layer 22 or may be a property of material from which the protective layer 22 is made." The Court addressed this statement previously. Kennedy appears to be distinguishing between a protective layer (e.g., a functional layer like the "placard" support layer in the '*790* and '164 patents) with inherent release properties and one that requires a coating. In the Smart Surface Placard, the Teflon coating only supplies release properties and does not also serve as the support layer. Nonetheless, this does not mean that Defendants were entirely unreasonable and were not acting in good faith.

13

The fact that a party has a patent does not mean that they cannot infringe the claims of another patent's broad "dominant" claims. *Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1110 n.9 (Fed. Cir. 1986)*. However, the issuance of a patent does provide evidence that Defendants' had a good faith belief of noninfringement.

[*40] MPT's focus on communications between Dronzek, Hurley and a third party regarding the eventual marketing and sale of a product is similarly unavailing. The important point is that Defendants had a good faith belief that they were not infringing. In such cases, there is nothing willful about planning to start a business. Their attempts to remain "under the radar" until they launched their product are typical of reasonable business actions. It is the rare business that will provide its competitors with advance notice that it has built what it believes to be a better product. When Marathon did launch the product, it did not hide that it would be used to perform the method. Instead, it candidly and prominently advertised its use to perform the method, a fact that Plaintiff used to its advantage in its infringement case. However, this is not the conduct of a party attempting to hide from a patent it believes to be infringed.

Moreover, MPT alleged infringement by Defendants almost immediately after the products hit the market. Defendants obtained counsel and responded with reasonable noninfringement and invalidity positions that they have maintained throughout this litigation. This is [*41] the conduct of reasonable actors acting in good faith and the Court does not believe a reasonable jury could conclude otherwise.

In sum, all of the evidence presented points to Defendants taking careful, measured action with respect to Plaintiff's patent rights. The Court therefore concludes that a reasonable jury could not have found clear and convincing evidence of willful infringement and JMOL is therefore appropriate on this issue.

e. New Trial [14]

14 Defendants have not moved for a new trial under *Rule 59*.

1. Jury Confusion

At trial Marathon went through a list of its customers and explained how each customer used the Smart Surface Placards. Some of the purchasers were resellers--i.e., middlemen who sold the Smart Surface Placard to the end user. At Defendants' request, the Court bifurcated liability and damages. In the liability phase of the trial, the jury was asked whether "any of Marathon's customers infringe any of claims 1, 2, 3, 4 or 6 of the *'790 Patent* or claim 1 of the '164 [*42] Patent?" The jury answered "yes" and in response to the next question indicated that all 6 of the claims at issue were infringed by "Marathon's customers . . . ." In the damages phase of the trial, the jury was asked "[i]f you find that a Marathon customer who bought the Smart Surface Placard performed all of the steps of the patents-in-suit in the United States, please identify the customer by name." The jury included two resellers in its list of customers. Defendants seek a new trial under *Rule 49(b)*, which states that "[w]hen the answers are inconsistent with each other and one or more is likewise inconsistent with the general verdict, judgment shall not be entered, but the court shall return the jury for further consideration of its answers and verdict or shall order a new trial." *Fed R. Civ. P. 49(b)*.

Defendants have waived the right to challenge the verdicts as inconsistent. After the jury's damages verdict was read, the Court and the parties' counsel engaged in the following exchange:

> THE COURT: Counsel, do you wish to see it? Before I discharge the jury is there anything further?
>
> MR. SHUNK: Your Honor, obviously we want [*43] to move the Court for a permanent injunction, but I assume that you want to receive that in writing.
>
> THE COURT: That is correct. And I'm really speaking of any other matters before I discharge the Jury. But yes, you have to brief that.
>
> MR. SHUNK: Yes. Nothing from the plaintiff, Your Honor.
>
> MR. COSTIGAN: Nothing.
>
> MR. WILSON: I'll renew my motion, but that's for after you get rid of the Jury. Nothing further.

"Most courts that have addressed the issue have held that a party's failure to object to an inconsistency between a special interrogatory and the general verdict waives the right to further deliberation or to a new trial." 9A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2513 pp. 226-27 (2d ed. 1995). The Federal Circuit recently addressed the application of Sixth Circuit law to this issue as follows:

> We apply the law of the pertinent regional circuit to the procedural rules regarding inconsistent jury verdicts and the waiver of objections to such verdicts. *Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1302 & n.1 (Fed. Cir. 2002)*. Under Sixth Circuit law, a party waives its objection to [*44] inconsistency in a jury's verdict if the party had an adequate opportunity to object but failed to do so.

*L & W, Inc. v. Shertech, Inc., 06-1065, 06-1097, 471 F.3d 1311, 2006 U.S. App. LEXIS 30617, *16 (Fed. Cir. Dec. 14, 2006)* (citing *Tennessee Consolidated Coal Co. v. United Mine Workers of America, 416 F.2d 1192, 1200 (6th Cir. 1969)*); *see also Mitchell v. Hallden Mach. Co., Nos. 92-5465, 92-5596, 92-5706, 92-5707, 1994 U.S. App. LEXIS 5640 (6th Cir March 23, 1994)* ("Failure to object to such an inconsistency in a timely manner constitutes a waiver of the objection.").

Because both of Defendants' counsel had ample opportunity to object to any inconsistency but failed to do so, the Motion is denied. [15]

> 15 The Court notes that in any event the verdicts were not inconsistent. The general verdict regarding infringement merely asked if "any" Marathon customer infringed. Moreover, evidence was presented that the resellers' customers infringe.

f. Conclusion [*45] **- Defendants' Motions & MPT's Motion to Strike**

The Court GRANTS Defendants' JMOL motion on the issue of willfulness. The Court otherwise finds that Defendants' contentions are either without merit or stricken.

PLAINTIFF'S MOTIONS

a. Enhanced Damages

A patentee may be entitled to trebled damages for infringement under *35 U.S.C. § 284*. The threshold question is typically whether infringement was willful, and the enhanced damages inquiry involves similar factors. *See SRI Int'l v. Advanced Tech. Lab., 127 F.3d 1462, 1464 (Fed Cir. 1997)* (explaining that "willful infringement . . . is the term designating behavior for which enhanced damages may be assessed"); *In re Hayes, 982 F.2d at 1545* (explaining that a "finding of willfulness may be a basis for an award of enhanced damages"); *Read Corp. v. Portec, Inc., 970 F.2d 816, 826 (Fed. Cir. 1992)* (noting factors of deliberate copying, the infringer's investigation, the duration of misconduct, remedial action by the defendant, the defendant's motivation for harm, and whether the defendant attempted to conceal its conduct). Here, [*46] the Court finds that enhanced damages are improper for the same reasons it granted Defendants' JMOL motion on willful infringement. Moreover, other enhanced damages factors such as the infringer's behavior as a party, the Defendants' size and financial condition and the closeness of the case all counsel against enhanced damages. *Read, 970 F.2d at 827*. The Court finds that Defendants--both relatively small companies--were forthright throughout the proceedings. Moreover, MPT's claims were by their nature difficult to prove. Because it does not have a patent on the placards, it had to prove direct infringement of the patented method as well as contributory or induced infringement by Defendants.

b. Permanent Injunction

The Supreme Court recently addressed injunctions in patent cases in *EBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 164 L. Ed. 2d 641 (2006)*. At issue in the *Ebay* case was the Federal Circuit's "general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances." *Id. at 1839*. A unanimous Supreme Court found this approach lacking, and held "that the decision whether to [*47] grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id. at 1841*.

Two concurrences were filed which addressed related points. Chief Justice Roberts (joined by Justices Ginsburg and Scalia) noted that "from at least the early 19th century, courts have granted injunctive relief upon a finding of infringement in the vast majority of patent cases." *Id.* Although this historical practice does not entitle a patentee to an automatic permanent injunction or justify a general rule in favor of injunctions, it does provide guidance to courts in the vast majority of run-of-the-mill patent cases. *Id.* Justice Kennedy (joined by Justices Stevens, Souter and Breyer) first acknowledged that "historical practice . . . is most helpful and instructive when the circumstances of a case bear substantial parallels to litigation the courts have confronted before." *Id. at 1842*. Justice Kennedy then noted certain patent practices that arose only recently. For example, [*48] some firms patent only a small component of a larger device, then use the threat of an injunction to charge exorbitant licensing fees to the manufacturer of the complete device. *Id.* Other patents such as business method patents are relatively new and have problems with "substantial vagueness and suspect validity." *Id.*

The core holding of *Ebay* is that a plaintiff must demonstrate the following four factors for a court to exercise its equitable discretion to grant a permanent injunction:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. at 1838.

First, the Court finds that MPT has suffered irreparable injury. MPT, along with the closely related company The Kennedy Group ("TKG"), obtained patents that allowed them to gain a dominant position in the sale of placards for use in the patented method. These patents are not an insubstantial [*49] component of a larger invention or a new form of patentable material. Instead, MPT has broad patent protection that reads directly upon the use of Marathon's Smart Surface Placard to practice the method. MPT invented a method, actively created a market, and established a strong market position and customer goodwill. Usurping this market by inducing or contributing to infringement will irreparably harm MPT. *See, e.g., Basicomputer Corp. v. Scott, 973 F.2d 507, (6th Cir. 1992)* ("The loss of customer goodwill often amounts to irreparable injury because the damages flowing from such losses are difficult to compute."); *TiVo Inc. v. EchoStar Communs. Corp., 446 F. Supp. 2d 664, 669 (E.D. Tex. 2006)* (finding irreparable harm where "Defendants compete directly with Plaintiffs" and the plaintiffs face loss of market share).

Second, monetary damages are not adequate to compensate for MPT's injury. Royalties will not stop the erosion of MPT and TKG's market. Another market entrant is likely to lead to a drop in prices, thus reducing MPT's royalties from Defendants and TKG as well as TKG's profits. Allowing Marathon to sell the Smart Surface Placard in [*50] the United States market will also damage MPT in that all placards have previously been provided by MPT. This implicates a significant impact on MPT's commercial reputation.

Third, the balance of hardships tips in favor of MPT. Only 10-15 percent of Marathon's total business [16] consists of sales of Smart Surface Placards. A large percentage of those are sold to Mexico and are not subject to an injunction. Thus, only a small percentage of Marathon's total sales will be prohibited by an injunction. As has already been noted, MPT is likely to face substantial hardship from the continued infringement of the patents in the United States.

> 16 Defendants did not address hardship to Polymeric.

Finally, the public interest supports an injunction. There is a general public interest in favor of strong patent protection, except in cases where an obvious public interest such as public health and safety exists. *Tivo, 446 F. Supp. 2d at 670*. Here, the method at issue is quite useful to the shipping industry. [*51] However, there is no critical public need for use of placards to practice the patented method, and MPT/TKG is more than willing to provide for customers' needs with a product that works in the vast majority of applications.

Accordingly, MPT is entitled to a permanent injunction under the traditional four-factor test.

Defendants next argue that MPT should be barred from seeking equitable relief by the doctrine of unclean hands. The Court is well aware of the conduct of all parties and counsel throughout this litigation. It finds that the parties and their counsel have acted professionally, complied with Court orders, and otherwise have generally taken good faith positions during this litigation. Accordingly, unclean hands has no application here.

Finally, the Court generally finds that Plaintiff's proposed language for a permanent injunction is proper. Although the Court agrees with Defendants that an injunction must be stated in specific terms and narrowly tailored to fit the specific legal violations, [17] their arguments regarding the scope of the injunction largely miss the mark. The jury has already found that the Smart Surface Placard does not have a substantial noninfringing [*52] use. Thus, any use of the placards will necessarily be to practice the method. However, the Court does agree that the prohibited products should be limited to those only "colorably different" from the Marathon Smart Surface Placard. *E.g., Int'l Rectifier Corp. v. IXYS Corp., 383 F.3d 1312, 1316-17 (Fed. Cir. 2004)*; *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc., 986 F.2d 476, 480 (Fed. Cir. 1993)*.

> 17 *Fed R. Civ. P. 65(b)*; *Gemveto Jewelry Co., Inc. v. Jeff Cooper Inc., 800 F.2d 256, 259 (Fed. Cir. 1986)*; *KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc., 776 F.2d 1522, 1525-27 (Fed. Cir. 1985)*.

As for Defendants' argument that placards sold in the United States may be shipped to Mexico for use there, the Court recognizes that use of the devices in Mexico does not infringe the patents. However, this does not justify allowing the sale of placards in the United States, based on the mere possibility [*53] that they may be shipped to Mexico or some other country for their use. Instead, it is most likely that placards will be used in the country where they are purchased. However, if Defendants wish to sell Smart Surface Placards in the United States for use in other countries, the Court notes that the Smart Surface Placards are capable of marking with print and graphics on the top coat. Products to be sold in the United States could carry a warning, permanently and prominently printed upon the top coat, explaining that the use of the placard to perform the method in the United States infringes the '*790* and '164 patents. Absent an appropriate disclaimer, Defendants and their employees, officers, agents, and those acting in concert therewith are permanently enjoined from using, selling, or offering to sell within the United States, or importing into the United States, the SmartSurface Placard or any product that is not colorably different from the SmartSurface Placard.

c. Attorneys' Fees

MPT seeks attorneys' fees under *35 U.S.C. § 285*, which states that the "court in exceptional cases may award reasonable attorney fees to the prevailing party." "Among [*54] the types of conduct which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit." *Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989)*. A case may be exceptional where the losing party is found to have acted willfully, recklessly, or with gross negligence in assessing and presenting its case to the court. *Eltech Systems Corp. v. PPG Indus., Inc., 903 F.2d 805, 810-811 (Fed. Cir. 1990)*.

MPT contends that Defendants were at least guilty of gross negligence in their defense. It argues that Defendants only had one reasonable defense--relating to the release coating--and that the defense was negated with the Court's *Markman* decision. Defendants nonetheless continued to press their release coating argument throughout the proceedings and into trial. MPT further notes what it perceives as bad faith litigation conduct regarding the substantially permanent attachment argument. It posits that this Court's denial of its infringement summary judgment motion hinged solely upon a Telofski [*55] DVD test that later turned out to have been the second test conducted after the first test failed.

With respect to the DVD test, the Court agrees with Defendants that it was not the reason the Court denied summary judgment on infringement. Rather, the Court found that MPT had failed to provide sufficient evidence to meet its burden of proving that Defendants' customers practiced the claimed methods. This distinction is important, because it also demonstrates why Defendants were not willful, reckless or grossly negligent in continuing to press their case after the *Markman* ruling. This case was not solely about the structure of the Smart Surface Placard. Because MPT's patents have method claims, it also had to prove that the method was practiced by someone. This is an inherently difficult inquiry where none of the direct infringers are parties to the suit. Morever, Defendants had reasonable invalidity and unenforceability defenses. For these reasons, the Court declines to find that this case is exceptional as would warrant attorneys fees.

However, MPT is entitled to costs under *Rule 54(d)*. Defendants argue that costs are prohibited under *28 U.S.C. § 1928* [*56] , which provides as follows:

> Whenever a judgment is rendered for the plaintiff in any patent infringement action involving a part of a patent and it appears that the patentee, in his specifica-

> tions, claimed to be, but was not, the original and first inventor or discoverer of any material or substantial part of the thing patented, no costs shall be included in such judgment, unless the proper disclaimer has been filed in the United States Patent and Trademark Office prior to the commencement of the action.

28 U.S.C. § 1928. Defendants then focus on the testimony of the inventor Petrou who explained that he witnessed Goodyear employees labeling and relabeling without placards. It was Goodyear's problems with messy removal, cleaning and multiple barcodes that led Petrou to invent the use of a placard device to practice the method of labeling and relabeling. Because labeling and relabeling without placards existed prior to Petrou's invention, Defendants argue that Goodyear was the "original and first inventor of any material or substantial part of the thing patented . . . ."

The parties have not provided and the Court has been unable to uncover any [*57] modern authority regarding *Section 1928*. However, older cases are in agreement that the statute refers to instances where the plaintiff has prevailed on some claims of the patent while other claims have been held invalid but not disclaimed or would have been held invalid without a disclaimer. *United Shoe Machinery Corp. v. Mathey, 117 F.2d 331, 334 (1st Cir. 1941)* (refusing costs for successful infringement plaintiff where other claims were invalid but not disclaimed); *John W. Gottschalk Mfg. Co. v. Springfield Wire & Tinsel Co., 75 F.2d 907, 908 (1st Cir. 1935)* (holding that "no costs can be allowed when a claim is held invalid and no disclaimer has been filed before suit is brought"); *Nat'l Elec. Signaling Co. v. De Forest Wireless Tel. Co., 140 F. 449, 455 (C.C.N.Y. 1905)* ("The statutes restricting costs upon filing a disclaimer after suit seem only to apply where a disclaimer is necessary to upholding the patent, and is filed for the purpose of saving it."); *Metallic Extraction Co. v. Brown, 110 F. 665, 668 (8th Cir. 1901)* (holding "although the decree below is sustained as to claim 1, no costs can be recovered [*58] by the complainant below . . ., since no disclaimer was filed by the complainant as to claim 4 before the present action was instituted"). Defendants did not argue at trial that Goodyear was a prior inventor such that a part of the patent would be invalid. Rather, Goodyear was an example of a company that was involved in the earlier practices that Petrou's inventive method improved upon. Accordingly, the Court finds that *Section 1928* is inapplicable to these facts. Because Defendants make no other arguments that MPT is not entitled to costs, the Court agrees that costs are appropriate.

CONCLUSION

Accordingly, the parties' motions are GRANTED in part and DENIED in part. The Court agrees with Defendants that they are entitled to JMOL that they were not willful infringers. The Court also finds that MPT is not entitled to attorneys fees. Accordingly, MPT is entitled to judgment that the patents are valid and infringed by Defendants, awarding damages in the amount of $ 3,561.64 plus costs, dismissing Defendants' counterclaims with prejudice and permanently enjoining Defendants and their employees, officers, agents, and those acting in concert therewith from using, selling, offering [*59] to sell, within the United States, or importing into the United States, the SmartSurface Placard or any product that is not colorably different from the SmartSurface Placard.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan

United States District Judge

Dated: 1/19/07

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation,	)	
Plaintiff	)	
-VS-	)	CA No. 04-12457-PBS
	)	Pages 1 - 35
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom,	)	
Defendants	)	

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ. and MICHAEL J. BONELLA, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
June 19, 2007, 2:50 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

P R O C E E D I N G S

THE CLERK: The case of DePuy Mitek, Incorporated V. Arthrex, Inc., et al, Civil Action 04-12457, will now be heard before this Court. Will counsel please identify themselves for the record.

MS. ELDERKIN: Dianne Elderkin on behalf of DePuy Mitek.

MR. BONELLA: Michael Bonella for DePuy Mitek.

MR. SABER: Charles Saber for Defendants Arthrex and Pearsalls.

MR. TAMBURO: Salvatore Tamburo for Defendants Arthrex and Pearsalls.

THE COURT: All right, we have cross-motions here, so it's not certain who should go first. Let me start with Arthrex because I wanted to deal with two minor issues before we hit the main one.

MR. SABER: Okay, yes, your Honor.

THE COURT: I may be misunderstanding. Are you still pressing the reverse doctrine of equivalents?

MR. SABER: Well, it's there only in this sense, your Honor, is that it is a -- their motion is on infringement, and it's based solely upon what the patent teaches. And we do believe, in fact particularly in light of your Honor's interpretation of the PE issue, which I know is not before us today, that we do think we have a viable

defense on doctrine of equivalents.

THE COURT: We're doing some research on this, so I don't pretend to be an expert. I've never seen anyone assert it before, and I don't know of any case where it's been successful. Do you?

MR. SABER: Well, it gets asserted a fair amount of times. What the plaintiffs made reference to is that it's not a basis where the Federal Circuit has solely affirmed based on a reversed doctrine of equivalents.

THE COURT: Do you view that as a jury issue or a judge issue?

MR. SABER: It's definitely a jury issue.

THE COURT: Why don't you explain it to me. I mean, I get a fair number of these patent cases.

MR. SABER: Sure.

THE COURT: It's the first time. So you are still pressing it?

MR. SABER: Yes, your Honor.

THE COURT: The bottom line is, I'm very skeptical. What's the argument? It's that what?

MR. SABER: In a nutshell, because I do agree it's not the major issue that we're here to talk about today, this is a patent that talked about how it used the first group of materials, which your Honor found that PE falls within and ultrahigh falls within, for purposes of adding handleability

aspects to the suture; and the second group, which is the PET, was added for strength. That was so it wouldn't be too weakened. Because you were using this material that was inherently not strong, inherently weak, you added in a little stronger material to get where you are.

Our product we think has absolutely nothing to do with that patent. Our product is a product that came out, it was the first one in the market. It was a high-strength suture to solve the strength issues, and it uses -- the product that the patent describes as weak is this incredibly strong product. So we're the polar opposite kind of product that's described by the patent in the polar opposite kind of way, which is exactly what this doctrine says.

As you know, of course, your Honor, we disagree with the claim interpretation you gave; but if it's correct, we assert that it's all the more reason why the PEs that we have, the ultrahigh, has nothing to do with what's being taught.

THE COURT: In any event, you're pressing it, so I'm going to resolve that on the summary judgment.

Now, on the tipping issue, why does that apply, because that's only at the end of it?

MR. SABER: It does have a purpose. The sutures are tipped, so for ease of use, and it restricts the movement. That's why we think it's a viable defense.

THE COURT: Again, that was in a footnote somewhere.

MR. SABER: Yes, I think that's right, but the reason that they raise that was because there aren't still defenses that are in the case to their --

THE COURT: I may resolve those in summary judgment. So now let's get to the main issue, which is the --

MR. SABER: Right, the "consisting essentially of" issue.

THE COURT: All right, so if I could just -- you know, I've now read the briefs, although not every piece of paper in the boxes. Don't I simply have experts who disagree? Why isn't that a trial?

MR. SABER: Not at all, your Honor. As I say, there are two issues that are before you, and the issue that you're going to really is: What does the evidence show in terms of the effect of coating on suture handleability? And we put in evidence which is undisputed by the defendants. This is every witness from DePuy Mitek and Ethicon, from the other side, without exception, the inventor of the patent, the people who developed their product, their 30(b)(6) witness, their director of research and development --

THE COURT: Right, they all say everyone uses coatings.

MR. SABER: Everyone. This is a universal --

THE COURT: I understand that everyone uses coatings, and I think that's absolutely correct in the record.

MR. SABER: That's right.

THE COURT: Sometimes it helps the operation of the suture. Sometimes it's harmful and hurts it, which is one of the reasons it was done, and at least there may be some argument that some coatings have a de minimis impact one way or another.

MR. SABER: There is no argument -- let me try and deal with both of those things that you said. On the handleability side of impact on the suture, there's no debate, it's always helpful. On the pliability side is where there's a debate on it, and that's why it's not part of this motion. But on the handleability side, there's absolutely no debate that coating is there. It is a universally known fact.

Your Honor, I really sincerely believe this is an absolutely simple case, that the other side --

THE COURT: Then why don't you just win it on a record? In other words --

MR. SABER: We should win on the record.

THE COURT: No, no, on a trial record, because here's the problem: You've got two of their experts, one of

theirs and one of yours actually, saying that it's subtle, or in a surgical setting with latex gloves on, you can hardly feel it. Why isn't that just creating a fact dispute?

MR. SABER: May I deal with both of the experts, if I could, please?

THE COURT: Yes.

MR. SABER: Dr. Brookstein first, their expert.

THE COURT: Right.

MR. SABER: Number one, of course, he had nothing to say about the evidence of what coating does. In fact, he said he doesn't have any idea. So then he offered some evidence. But it's very revealing what he says in his declaration, he said in his deposition, and he says in his report about why his testimony is relevant, because we think it's the answer as to why it doesn't create a factual dispute. Dr. Brookstein testified that to -- so it doesn't affect the basic and novel characteristics because it doesn't transform the suture into something else. It doesn't stop it from being in direct intertwining contact. It doesn't stop it from being a suture.

The quote that he said, and if I may just have a moment to get what it is, he said, "There's not enough coating to transform the braided FiberWire materials into another structure or to cause it to lose its characteristics that are attributable to the dissimilar yarns being

braided."

And then we asked him, "What do you mean by that?" And he says -- well, that's where, you know, this magic or miracles quote that you've seen. He says, "By some magic or by some miracle, it makes it into something that it's not."

Well, the tests that Dr. Brookstein used, that you have to transform the product into something else that it's not, has been specifically rejected by the Federal Circuit in the PPG case which we cite to your Honor. In the PPG case, the plaintiff there made a very, very similar argument, that argument. That was a case about glass, and the claim said, like the claim does here, that the glass has to do certain things. It had to do with color and something else. I can't remember exactly what it was. And the plaintiff argued, to have a material effect, it has to literally take away those characteristics that are in the claim. And the Federal Circuit said, "No, that's not the test."

If I may read to your Honor from the PPG case: "We are fortified in our interpretation of the specification by the fact that PPG has not offered a satisfactory alternative construction. PPG's position at trial was that a significant change in glass properties is one that results in a glass product that does not satisfy the color or transmittant limitations of the patent claims." Just what Dr. Brookstein is saying here: You have to transform it into

something it's not. And the Federal Circuit said, "That proposed definition is suspect, however, because it would mean that any residual sulfur compound in the glass composition --" sulfur was what was being added there -- "could avoid the 'consisting essentially of' limitation only by taking the glass outside the other limitations of the patent. If that definition of significant effect were adopted, it would have the effect of converting the critical claim language from 'consisting essentially of' to 'comprising.'"

So, in other words, that's exactly the evidence that they put in from Dr. Brookstein: You have to transform it into something. He was consistent. It's the only thing his report says. It's the only thing his declaration says. It's the only thing he said in his deposition: That's what I consider no material effect. It's got to transform it into something. It's not in direct intertwining contact.

Well, what does that mean? That means you just wrote that claim term out of the patent. The Federal Circuit said that's not the way to construe a "consisting essentially of" test. And that's why Dr. Brookstein, even if he were competent, doesn't raise an issue of fact. It's plain and simple. He didn't do any tests of coated versus uncoated. He just had this test of transformation: You have to transform it somehow by magic and miracles. And that's the

test that's been rejected by the Federal Circuit.

Your Honor said, "Does it have a material effect on the handleability of the suture?" That's what your Honor said in your order. We agreed with that, and he didn't put in any evidence on that. It was only in the context of having to transform the product.

Now, one last word on Dr. Brookstein. In their most recent brief, they tried to recharacterize his testimony and said, well, he said that compared to the benefits you get of the two different sutures, any added benefit you get of coating is minimal. The problem is --

THE COURT: Does he say that?

MR. SABER: No, he never said that. He never said that. First of all, he never tested coated versus uncoated, and what he said in his declaration, which is what plaintiffs rely upon, is, he said, "In other words --" this is the very paragraph they rely upon -- "the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided." That's his opinion. That's legally incorrect, and that's why we believe, your Honor, that Dr. Brookstein simply does not raise a genuine issue of material fact here.

Now, if I may turn to Dr. Burks, which is the other piece of evidence that they tried to offer.

THE COURT: That's your expert?

MR. SABER: That's right. As your Honor correctly noted, Dr. Burks is not their expert. He's someone that we put on, and we had him do some of these kind of field tests. He just felt some sutures and so forth.

The first reason why Dr. Burks doesn't create an issue of material fact, number one is, in their brief they told your Honor, "We don't think Dr. Burks has competent evidence." It's hornbook law, your Honor, that you can't rely on evidence which you believe to be incompetent to defeat a summary judgment motion. I don't think your Honor has to go any further than that with Dr. Burks to say, based upon plaintiff's own position of Dr. Burks, that it's not evidence that is of the quality to defeat a summary judgment motion. They say it should be excluded, and they give a whole pile of reasons. I won't go into that, but I think that's reason one.

Reason two, if you look at Dr. Burks and what he did, first of all, he did six blind tests. He did it for his report. He did them at the deposition, all right? Each time he got it right. When this issue of subtle came up, he explained what it meant. He said: If you do it a hundred times, you might not get it right every time. But, you know, going back to the PPG case, it says, is this something that's of importance to someone in the market, right? They never

asked him that.

THE COURT: What does your expert say?

MR. SABER: Well, our expert relies upon what everyone in the marketplace says, which is all the patents --

THE COURT: But did your expert do his own testing and say that it made a material difference?

MR. SABER: No, our expert didn't.

THE COURT: I disagree with either side's position that I can do it off of the specification because the specification says all things to all people. It can help; it can hurt. I mean, I think you have to look at the specific product to see whether it makes a material difference.

MR. SABER: Actually, I'd agree with that. I think that this notion of looking at the patents probably doesn't answer the question. It comes down to the question of the evidence.

THE COURT: So if you don't have a doctor or an expert who's tested it in a surgical setting and says it makes no difference --

MR. SABER: Well, we do. Of course, Dr. Burks did that, though we weren't the ones that offered that for purposes of summary judgment. The other side did. He got it right every time. But that's not the test. The test really is, this is what one of ordinary skill would mean. And that's where every teaching and everything that's known in

the field would matter. I mean, that's the evidence that, frankly, ends this case. It begins this case, and it ends this case. It is so universally known. It's like having a trial over whether the world is round or flat. You don't need to do it because it's so universally accepted. So to get into some sort of debate about tests where anyone can of course create --

THE COURT: But now you're moving me back in the specifications.

MR. SABER: No.

THE COURT: You're absolutely correct that coatings were universally known, and, as far as I could tell, frequently used in the field.

MR. SABER: That's correct.

THE COURT: And the patent in a sense taught against it in the sense of some of them apparently didn't work very well and actually impeded the handleability of the suture.

MR. SABER: The pliability of the suture.

THE COURT: The pliability, right, fair enough. Other coatings, they said, well, maybe you can use, and maybe you don't have to use. I mean, they basically left it up to the user, right, to use a coating? So some coatings might be effective, and some coatings may not be effective, and some coatings may actually substantially change the handleability

and some not, right?

MR. SABER: Never, it never ever says that. It never ever says that. It never ever questions the universally known fact that coating helps handleability.

THE COURT: No, I disagree with that. It says you don't need to use them.

MR. SABER: That's what their invention was allegedly about. Their invention was allegedly about -- it never worked. They never could make a product under it, but their invention was allegedly about, if you use enough of this lubricious material, you won't need coating.

THE COURT: You won't need coating.

MR. SABER: That's right, and that's exactly, your Honor, why we win this case, one hundred percent why we win this case.

THE COURT: Why wouldn't you win it on a record in front of a jury instead of -- in other words, if I don't have one of your people saying it doesn't make a difference and I --

MR. SABER: Well, you do, you know, and our experts put it in, but it's based on the record, your Honor. It's --

THE COURT: I understand. You keep pushing me back; you keep agreeing with me that I can't look at the specification. I need some admissible evidence, admissible evidence that the coating on your product makes a difference.

MR. SABER: Your Honor, let me tell you what it is, if I may.

THE COURT: Okay.

MR. SABER: First of all, it starts with every patent in the field, not this patent, every patent in the field, every article in the field.

THE COURT: Well, do you have an expert that says that the coating on your product makes a material difference?

MR. SABER: Well, yes. Dr. Mukherjee, you know, looked at all the evidence, and he said that. Now, the specific evidence with respect to FiberWire comes from Arthrex, and Arthrex says -- and, again, this is undisputed -- Arthrex said their coating is on the FiberWire for reasons of handleability to ease -- to do the better knot tie-down.

THE COURT: Do you have an expert report in there that says it materially improves on the suture?

MR. SABER: Well, based upon that evidence, yes, your Honor. I mean --

THE COURT: So, you know, you're going round about.

MR. SABER: Well, I don't want to tell you --

THE COURT: Who says -- is there any expert in this record who says, "I tested this, and it substantially improves the coating over if there were no coating"?

MR. SABER: I want to divide up the summary judgment record from the other record in the case, just to be clear on this answer. What the record for summary judgment is, is that our expert looked at the state of the evidence, which included --

THE COURT: That's Burks?

MR. SABER: No, no. This is Dr. Mukherjee.

THE COURT: This is Mukherjee.

MR. SABER: Right, which is based upon the state of the evidence. It included Dr. Burks, by the way, but, you know, he's the one that concluded, based on the state of the evidence, based upon Arthrex's statements that were being done and other things that he included, therefore, it's my opinion that there's no -- that the coating creates a material effect on handleability.

THE COURT: So if I read Mukherjee, it's going to say, "I did testing on the coatings," or, "I've looked at this, and it makes a difference"?

MR. SABER: He, I believe, did some of that, but that testing -- there was some testing done by a Dr. Gitis and by Dr. Burks. They're the ones who actually did the tests. But we didn't believe because we don't, in any -- there isn't a case alive where someone can't create some sort of issue about how the test was done. We understand that, and that's why it's not part of the summary judgment record.

We don't believe it's necessary to be part of the summary judgment record, and that's why we didn't put it in. The tests from Dr. Burks and from Dr. Gitis were not put into the summary judgment record. That's why I wanted to make that distinction between the two for your Honor. It's there. It's just not part of the summary judgment record because we don't think you need to do it to get to summary judgment.

THE COURT: But you're making -- you want me -- I know nothing about your area. I know nothing, nothing.

MR. SABER: Sure.

THE COURT: I know what you told me is true, based on having had this case, that the coatings are used frequently.

MR. SABER: Right.

THE COURT: And my guess is that when the patent was amended to add the "consisting essentially of," they were not thinking about coatings but ended up with that as a problem for them.

MR. SABER: That's correct, your Honor.

THE COURT: They were thinking about bio-absorbable yarns, and they ended up with a big problem.

MR. SABER: That's probably correct, yes, but that's the legal effect of what they did.

THE COURT: That's the legal effect of what they did.

MR. SABER: That's right.

THE COURT: And so now I've got this issue of, I don't know whether every single coating out there makes a material difference. I don't. I know that they're often used, but I don't know whether that makes a material difference if that's the standard. I don't know that.

MR. SABER: Well, as I say, I think all we have to do is to look to the evidence on that, and that's why I hate to go harken back to that, but they don't dispute our evidence. They don't say our evidence is wrong. And I'm not talking about the '446 patent specification. I'm talking about what people in the field have uniformly said, uniformly said.

THE COURT: But have they said it on your product?

MR. SABER: They've said it about all coatings, about all coatings.

THE COURT: I just can't believe that all coatings are created equally.

MR. SABER: All coatings are created to improve the handleability of the suture, yes, your Honor, and all the evidence says that.

THE COURT: But I don't know from my own knowledge that they in effect do that; in other words, whether it's a material difference.

MR. SABER: Well, if the evidence all shows that,

all shows why coating is added, is to help on this knot tie-down, if all the evidence shows that, every piece of evidence shows that, we think your Honor is entitled to rely upon that evidence. If they disagreed with that, if they had some evidence that somehow --

THE COURT: All right, well, let me turn to them.

MR. SABER: -- somehow -- let me just finish the thought -- somehow that FiberWire was different and it wasn't true, it's true for every suture in America except for FiberWire, don't you think they would have come forward with something? And they didn't.

THE COURT: Well, here's the question. I mean, I'm stuck on a record where neither of you are giving me what I want, which is someone who looks at that wire and says, "Yes, it makes a difference," or, "No, it doesn't." So why didn't your expert do that?

MS. ELDERKIN: Well, for several reasons, your Honor. First of all, we submit that the disclosure in the specification -- I know you're not going there, but just for the record I'll say, the disclosure in the specification is not as Arthrex has characterized it in their brief, which says that coatings may be used to further enhance the properties, surface coatings --

THE COURT: So you have to concede that some coatings are going to materially enhance it?

MS. ELDERKIN: Some coatings will materially enhance it or materially detract from it.

THE COURT: Or materially detract, but I won't know which it is until someone looks at it and tests it.

MS. ELDERKIN: Well, and somebody did look at it and tested it, and it was actually Dr. Burks, their expert. He looked at it. He did side-by-side analyses of what they purported to be coated and uncoated samples, and his testimony, which has not been rebutted, is, "It's a subtle difference. It's very close. If I had my gloves on as I use it in surgery, which is the real environment in which I use these sutures, I might not be able to tell the difference." I mean, that is expert testimony about that there's not a material difference.

THE COURT: I'm a little floored on this. I know you're both pushing me to extremes that I should decide this based on the specification, and I'm not going to do that, but I'm just curious as to why you don't have an expert who's actually on your own team who said that.

MS. ELDERKIN: Well, there are several reasons for that, your Honor. One of the reasons is that my client, Mitek, does not have access to the samples that are needed to do this analysis.

THE COURT: Can't you go out in the marketplace and buy it?

MS. ELDERKIN: No, because you have to get the suture coated. You can buy the coated suture, we can certainly buy that, but you can't buy uncoated suture on the marketplace.

THE COURT: Have you ever heard of discovery?

MS. ELDERKIN: Well, we did ask for those samples, and we actually went over to the United Kingdom where the samples were made to see where they pulled them off of the manufacturing line, and determined that the samples that they had given us -- this was at the end of discovery -- were not truly coated versus uncoated samples.

THE COURT: Here's my problem: I don't agree with either side that I can resolve it for one person or the other person off of the specification. So now I'm into this record, and I've got this odd position that neither of you have an expert who themselves is saying it makes a material difference or it doesn't, and you're relying on their expert's acknowledgment that the differences are subtle. The only person that you have in your arsenal is their expert, who you, as he says, attack his competence, but, more significantly, you know, is obviously doing it in the context of supporting their case. It's just an odd case. It's odd.

MS. ELDERKIN: I would agree it's odd, your Honor. We also have Dr. Brookstein, though, is also one of our experts.

THE COURT: But he never actually says it, right?

MS. ELDERKIN: He says -- he analyzed the suture. He went over. He watched it being made. He saw how the coating was applied, which none of their experts did. He watched how it was applied. He talked about it in his expert report, which is Exhibit 6 to our motion. He talked about how the sutures passed very rapidly through a solution of coating and then passed through rollers and dried. He talked about how much coating there is on the suture. He measured how much coating is on the suture.

THE COURT: But did he try it in surgery?

MS. ELDERKIN: No, but he determined that it was merely a surface coating.

THE COURT: So --

MS. ELDERKIN: He looked at the sutures under the photomicrograph, and he saw that it was just a surface coating. And if I could refer your Honor to --

THE COURT: But if that substantially improved the lubriciousness of it, why isn't that materially improving the basic and novel characteristics of the invention?

MS. ELDERKIN: Well, your Honor, if I could --

THE COURT: Sure, go.

MS. ELDERKIN: Somehow we're up on your screen here. I would like to bring us up to your Honor's definition of the basic and novel characteristics, and particularly

Item No. 4 there. These are the basic and novel characteristics as your Honor defined them, and I don't think there's any dispute about the first three, so I won't even spend time on that. But the idea of the basic and novel characteristics was to have the suture, these dissimilar yarns, "So as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture."

And as your Honor explained in your Markman order, the idea of the invention in the Mitek patent is to use these dissimilar heterogeneous yarns with different properties, to braid them together in a certain way to mechanically blend them to get an improved suture. And that is the basic and novel characteristic that we are looking at to determine whether a coating affects that, and that's exactly what our Dr. Brookstein has explained. He said: I've looked at this. I've looked at the coating. I can see it is just a surface coating, and that surface coating is not affecting in any way the ability of these heterogeneous yarns, which retain their morphology -- they're not all gunked together and blended together or melted together or glued together by some thick coating -- there is nothing in this coating that is affecting the ability of these yarns, the morphology of the yarns, the ability of them to contribute to the overall properties of the sutures. They retain their individual characteristics.

They're not significantly sacrificing the physical properties of the constituent elements of the suture.

And, if you remember, Arthrex's proposed construction used different language. They wanted you to rule that it would not significantly affect the physical properties of the suture. And your Honor's construction, which we contend is correct, is that whatever this additional element is, it cannot sacrifice the physical properties of the constituent elements of the suture, and that's what Dr. Brookstein says in his declaration.

THE COURT: I think Dr. Brookstein's declaration is certainly relevant. It's just not a bingo for you because he doesn't actually check to see whether it improves the pliability and handleability.

MS. ELDERKIN: With all due respect, your Honor, I don't know that that is really the issue under this construction of basic and novel characteristics.

THE COURT: It's both. It's got to improve the handleability and pliability without impeding or sacrificing the physical properties. So he tells you it isn't sacrificing anything, but if it also improved handleability, wouldn't that take you out of the infringement under a "consisting essentially of"?

MS. ELDERKIN: Under this construction of basic and novel characteristics, I would argue that it would not.

THE COURT: I'm not sure I agree, but, in any event, what other issues are left in this suit? Let's say I went to trial on infringement. Are there other defenses?

MR. SABER: Oh, yes, your Honor. I mean, if we go to trial, not only do we have the issues that we've been talking about today, but then there's the whole series of invalidity defenses and inequitable conduct defenses. As you may remember --

THE COURT: So is there obviousness and then possibly anticipation?

MR. SABER: That's correct, that's correct. Now, we moved on one anticipation grounds. There actually are several invalidity grounds that were put forward, but we didn't put them in a motion to your Honor. The one that we did put into a motion, your Honor, on anticipation on the Chesterfield patent, your Honor denied that motion. The other side had a motion on the inequitable conduct piece. Your Honor also denied that as well.

THE COURT: The inequitable conduct I'll put into the "manana" world.

MR. SABER: Well, at the end of the day, it's something for the Court to determine, correct.

THE COURT: Right. So if I were to do a trial just on infringement, would that make sense, or should I do it on everything, because it sounds like a little infringement

trial would take two days?

MR. SABER: Well, I don't know whether it would or it wouldn't.

THE COURT: I'm always a little bit -- a week. I mean, it's not a big trial.

MR. SABER: Sure. I would say this, though, that, you know, of course, if we prevailed at the infringement trial --

THE COURT: It's over.

MR. SABER: So you wouldn't need to go to the validity issues. If we didn't prevail on it, then obviously you'd need to go to the validity issues. So I haven't really thought about whether that makes sense.

THE COURT: Doesn't that make sense to do a little one-weeker this summer?

MR. SABER: I don't know if that makes sense to bifurcate it that way. It's just --

THE COURT: Well, think about it because as you're gathering from what I'm saying, I'm not sure I go with the tipping or the reverse doctrine. I have to learn what the reverse doctrine of equivalents is.

MR. SABER: Yes, we don't think it's the major issue, obviously, your Honor. That's why --

THE COURT: But could you do it in a week this summer? Then, if there's no infringement, you're off the

hook, your patent remains --

MS. ELDERKIN: I'd like to consider that, your Honor, but --

THE COURT: -- wholly intact, and we go on.

MR. SABER: Your Honor, I don't know the answer to that question. I mean, my experience in these kinds of trials is, of course, they do tend to take longer.

THE COURT: Well, for sure, if I put in all the rest of it, it would. I'm just trying to figure out what's the most efficient. So if it took me two weeks to do the stuff with the defenses in it, it might be worth it from your point of view. Where are you from? Minnesota, right?

MS. ELDERKIN: Philadelphia, but we have witnesses from all over the place, so --

THE COURT: So you're Philadelphia. Where are you from?

MR. SABER: I'm from Washington, though born here. I was born in Boston, but I've lived in Washington for the last --

THE COURT: Inside the city?

MR. SABER: I was actually born in Boston, but I was raised in Brockton.

THE COURT: Okay. Well, welcome home to you. So the question I'm really thinking out loud on is whether it makes sense to do just a little infringement trial, which

would be very straightforward and easy for a jury. I mean, it's really -- and I could possibly even do a judgment as a matter of law, once I heard both experts really talk, after the fact. Or does it make more sense to do it with all the defenses in the trial? I'm thinking one week on infringement.

MS. ELDERKIN: I agree, your Honor, if we were only doing infringement, easily within a week.

MR. SABER: I'm just not sure about that because there are actually several experts that are involved. In fact, one of the issues that we do have is, there was kind of a side issue when we were before your Honor the last time, not actually -- we didn't talk about it with your Honor, but there was some motions with respect to Dr. Gitis, and the parties have kind of put that on hold because it would be --

THE COURT: I don't remember the issue.

MR. SABER: Oh, Dr. Gitis had done some tests. They weren't part of the summary judgment record, and the other side had raised questions about the propriety of Dr. Gitis' tests and had gone to the magistrate. Your Honor, that was the computer glitch issue and --

THE COURT: You know, you must think I'm having sort of a senior moment, but I've just had so much, I don't remember it.

MR. SABER: The details of it don't really matter.

The point is that your Honor issued a ruling that said that we could supplement Dr. Gitis' report, and they would have a right to depose him on that.

THE COURT: Sure, that seems fair.

MR. SABER: Right, that's the way that played out. The only thing is, because of the pendency of the summary judgment motion, the parties put that in abeyance, only to do that if it became necessary.

THE COURT: Well, why don't I do this: I could do a little trial in August. That would give you plenty of time to do that, right, and any supplementation of reports?

MS. ELDERKIN: As long as we don't have any dispute about what the supplementation of the report is. I fear that we will. Your Honor's order was that they could supplement the reports to correct typographical errors.

MR. SABER: Well, that's not correct, but -- that's not correct.

THE COURT: Now it's coming back to me. There were some calculation problems.

MS. ELDERKIN: There were calculation problems and alleged computer virus problems.

MR. SABER: And the computer virus stuff was what we couldn't fix, and the rest of the stuff we could.

THE COURT: Well, let me ask you this point blank. What I'm expressing to you is some frustration here that

neither of you has an expert that just says, "I tried this out in the setting for which it's used, and it does or does not make a difference." So the question really is, I don't -- I feel as if there's, at least based on your expert's concession of subtlety, that there's at least a fact question here. But it's an odd record for me. I usually have someone saying point-blank, "I tested it, and it's X."

MR. SABER: May I finish on Dr. Burks because on this whole subtlety thing, they tried to create this issue about gloves to try and say that "Well, it might be different through gloves." That's not evidence, your Honor. The man did a report. The report is in the record. The record says exactly what your Honor is asking for. He did the tests. He said, "In my opinion, the coating makes a material effect." He's a surgeon and so forth. That was his report, right?

Then they took his deposition, and they're trying to create these things about the dry versus wet issue and the gloves versus nongloves issue. On the gloves they said, well, you know, it might have made a difference. He didn't say it did. That's not evidence, your Honor. That's speculation.

THE COURT: So that's why I'm asking both of you. I always hate to reopen discovery, but let me just ask you this. I mean, do you both agree that this would be used in a setting where people are wearing gloves and have got -- and

I'm saying slurpy things, you know, like blood and --

MR. SABER: I think sometimes it is, and sometimes it isn't.

THE COURT: Fluids and that sort of thing, so --

MS. ELDERKIN: Dr. Burks's testimony is that it would be, other than in a cadaver surgery, he said --

THE COURT: But neither of you have tested it in that setting to see if it makes a difference.

MR. SABER: But, your Honor, because -- there's something about common sense that's just missing here, your Honor.

THE COURT: I don't have common sense because I wasn't trained as a surgeon, so I don't know. I just don't know. And so on this record, I don't know. And I wish I had a surgeon or somebody who is an expert in this field who tested it and said, "Yes, it does make a difference," or, "No, it doesn't."

MR. SABER: Right. Well, as I say, Dr. Burks did. It's in this record.

THE COURT: With gloves and in a sort of wet situation?

MR. SABER: He did it in the wet situation. He didn't do it with the gloves.

THE COURT: All right, well, I'll read it, but I'm simply telling you what my frustration was, which is that

neither side really did it for me, and I'm not sure where that would leave it for a jury.

MR. SABER: And may I add just something else because they said that we didn't give them samples. We gave them samples before this case started. We gave them samples twice during the case. They've had all the samples. They haven't done any tests. They actually did do some tests when we gave it to them the first time. They haven't produced the tests to us. I think we know why. They're claiming work product privilege on it. I think we know why.

You would think, if some things were different, that what everyone in the marketplace knows, that they would have done a test to show that it's not true. And that was frustrating --

THE COURT: You know, you're making a very good point here, which I'm not going to reopen discovery on experts. You'll finish your tests. You'll either meet your burden or not meet it. You'll put on your expert. You know, I have some sense of frustration because the obvious thing isn't in my record, somebody just saying from your side it doesn't make a difference.

MS. ELDERKIN: And, if I may, your Honor, I would like to refer you to Dr. Burks's report because it is attached as an exhibit to our brief, and I'm sorry I don't have the number for that particular exhibit. He nowhere says

that there's a material difference in that report. Counsel represents that he did.

THE COURT: Well, I will relook at those. As I said, I've read the briefs. I haven't had a chance to go through every one of these, and I will go through them, but right now I'm setting a trial date just on infringement. Why don't we do it in mid-August. We will not reopen discovery. No one's asking me for that. So that's it. We'll have trial, and once I see the trial, maybe I'll agree with one side or another based on the weight of the evidence. I'm not seeing it in this record.

So, Robert, when can we do it in August? August 6?

MR. SABER: Yes, I really fear whether that's going to give us the time to get all the pretrial stuff done. It's now June 19. It's six, seven weeks, and there's all kinds of --

THE COURT: What else? You haven't told me what else.

MR. SABER: Well, just with getting the exhibits and getting all the in limine motions and all of that before your Honor.

THE COURT: I'm just doing infringement, the little baby piece. I'm not persuaded that we can't do this. How old is this case? It's old now, right?

MR. SABER: I just think that's a little quick. If we can maybe do it in a couple months after that.

THE COURT: Let me ask you this: Is that your vacation?

MR. SABER: No, it isn't.

THE COURT: I'm not here to destroy someone's vacation.

MR. SABER: No, no, it really was a fear that that is simply not enough time.

THE COURT: Let me do this: I'm going to set it for the 6th. We'll give you a pretrial order, and then you see if everyone can do it. I'm doing it on the 6th because most people take the end of August. If you can't do it then, I'll see -- if some of your experts can't make it, we'll see when they can. But it's basically, as far as I'm concerned, pretty much teed up. You do this deposition in the next few weeks. You can do it, right?

MR. SABER: I suspect we could. We probably could get them the report within the next week and a half or so, thereabouts. The deposition, your Honor, only is about three or four hours, something like that, so I'm sure we could get that done.

THE COURT: Sure, it was just a cleanup calculation is what it should be.

MR. SABER: I think we can get that done. I

just --

THE COURT: Now, let's go off the record for a minute.

(Discussion off the record.)

MR. SABER: Your Honor, we had prepared a PowerPoint for today. I don't know if you'd like a copy of it, your Honor.

THE COURT: I would love it.

MR. SABER: Okay, and I have plaintiff's PowerPoint too.

THE COURT: I'd love them.

MR. SABER: Thank you, your Honor.

MS. ELDERKIN: Thank you.

THE COURT: Thank you. I'm sure I won't see you before then. Have a nice July 4 weekend.

MS. ELDERKIN: Thank you.

THE CLERK: The final pretrial is July 31 at 4:00 p.m. That will be in the pretrial order. You'll get that, okay?

(Adjourned, 3:35 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter, do hereby certify that the foregoing transcript, Pages 1 through 35 inclusive, was recorded by me stenographically at the time and place aforesaid in Civil Action No. 04-12457-PBS, DePuy Mitek, Inc. V. Arthrex, Inc., et al, and thereafter by me reduced to typewriting and is a true and accurate record of the proceedings.

In witness whereof I have hereunto set my hand this 10th day of July, 2007.

/s/ Lee A. Marzilli
LEE A. MARZILLI, CRR
OFFICIAL FEDERAL COURT REPORTER

EXHIBIT 4

DOCKET NO. ETH-782
Joint Inventors

A S S I G N M E N T

Serial No._____
Filed_____

WHEREAS, Mark Steckel, Citizen of the United States of America, residing at 9819 Farmdale Way, Maineville, Ohio 45039 (hereinafter called "Assignors"), have made certain new and useful inventions or discoveries relating to

STERILIZED HETEROGENEOUS BRAIDS,

for which thsy have this day executed an application for Letters Patent of the United States; and

WHEREAS, Ethicon, Inc., a corporation of the State of Ohio, (hereinafter called "Assignee"), is desirous of acquiring Assignors' entire right, title, and interest therein:

NOW, THEREFORE, BE IT KNOWN that for and in consideration of the sum of One Dollar and other valuable considerations to them moving, the receipt of which is hereby acknowledged, Assignors have sold, assigned, and transferred, and do hereby sell, assign and transfer unto said Assignee their entire right, title and interest in and to all said inventions and discoveries disclosed in said application whose identification above by serial number and filing date, when available is hereby authorized, and in and to said application, all substitutions, divisions, and continuations thereof, and in and to all Letters Patent, United States and foreign, that may be granted for said inventions and discoveries, and in and to all extensions, renewals, and reissues thereof, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by Assignors if this Assignment and sale had not been made;

And Assignors hereby authorize and request the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

And for the consideration aforesaid, Assignors covenant and agree with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title they warrant unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignors further covenant and agree that they will, whenever requested, but without cost to them promptly communicate to said Assignee or its representatives any facts known to them relating to said inventions and discoveries, testify in any interference or legal proceedings involving said inventions and discoveries, and execute any additional papers that may be necessary to enable said Assignee or its representatives, successors, nominees, or assigns to secure full and complete protection for the said inventions and discoveries or that may be necessary to vest in said Assignee the complete title to the said inventions and discoveries and patents hereby conveyed and to enable it to record said title.

RECORDED 6023 FRAME 915

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

DEPUY MITEK
EXHIBIT 562
04cv12457

IN TESTIMONY WHEREOF, Assignors have hereunto set their hands and seals this 17 day of FEB , 1992.

Mark Steckel (L.S.)

STATE OF OHIO)
) ss.
COUNTY OF)

BE IT REMEMBERED, That on this 17 day of February, 1992, before me, a Notary Public, personally appeared Mark Steckel, who I am satisfied are the persons named in and who executed the foregoing instrument in my presence, and I having first made known to them the contents thereof, they did acknowledge that they signed, sealed, and delivered the same as their voluntary act and deed for the uses and purposes therein expressed.

Mary L. Flesher
Notary Public

MARY L. FLESHER
Notary Public, State of Ohio
My Commission Expires June 8, 1996

RECORDED
PATENT & TRADEMARK OFFICE
FEB 19 92

RE6023 FRAME946

EXHIBIT 5

DOCKET NO. ETH-788
Joint Inventors

07/838511

A S S I G N M E N T

Serial No._____
Filed_____

WHEREAS, Alastair W. Hunter, Dennis D. Jamiolkowski and Arthur Taylor, Jr., Citizens of the United States of America, residing at 516 Spring Valley Drive, Bridgewater, New Jersey 08807; 20 Fawnridge Drive, Long Valley, New Jersey 07853; and 1217 East Second Street, Plainfield, New Jersey 07062 (hereinafter called "Assignors"), have made certain new and useful inventions or discoveries relating to

STERILIZED HETEROGENEOUS BRAIDS,

for which they have this day executed an application for Letters Patent of the United States; and

WHEREAS, Ethicon, Inc., a corporation of the State of Ohio, (hereinafter called "Assignee"), is desirous of acquiring Assignors' entire right, title, and interest therein:

NOW, THEREFORE, BE IT KNOWN that for and in consideration of the sum of One Dollar and other valuable considerations to them moving, the receipt of which is hereby acknowledged, Assignors have sold, assigned, and transferred, and do hereby sell, assign and transfer unto said Assignee their entire right, title and interest in and to all said inventions and discoveries disclosed in said application whose identification above by serial number and filing date, when available is hereby authorized, and in and to said application, all substitutions, divisions, and continuations thereof, and in and to all Letters Patent, United States and foreign, that may be granted for said inventions and discoveries, and in and to all extensions, renewals, and reissues thereof, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by Assignors if this Assignment and sale had not been made;

And Assignors hereby authorize and request the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

And for the consideration aforesaid, Assignors covenant and agree with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title they warrant unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignors further covenant and agree that they will, whenever requested, but without cost to them promptly communicate to said Assignee or its representatives any facts known to them relating to said inventions and discoveries, testify in any interference or legal proceedings involving said inventions and discoveries, and execute any additional papers that may be necessary to enable said Assignee or its representatives, successors, nominees, or assigns to secure full and complete protection for the said inventions and discoveries or that may be necessary to vest in said Assignee the complete title to the said inventions and discoveries and patents hereby conveyed and to enable it to record said title.

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

REEL 6023 FRAME 942

DEPUY MITEK
EXHIBIT 563
04cv12457

IN TESTIMONY WHEREOF, Assignors have hereunto set their hands and seals this 18th day of February, 1992.

Alastair W. Hunter (L.S.)

Dennis D. Jamiolkowski (L.S.)

Arthur Taylor, Jr. (L.S.)

STATE OF NEW JERSEY)
) ss.
COUNTY OF SOMERSET)

BE IT REMEMBERED, That on this 18th day of February, 1992, before me, a Notary Public, personally appeared Alastair W. Hunter, Dennis D. Jamiolkowski and Arthur Taylor, Jr., who I am satisfied are the persons named in and who executed the foregoing instrument in my presence, and I having first made known to them the contents thereof, they did acknowledge that they signed, sealed, and delivered the same as their voluntary act and deed for the uses and purposes therein expressed.

Judy A. Reilly
Notary Public

RECORDED
PATENT & TRADEMARK OFFICE
FEB 19 92

RR6023 FRAME 943

EXHIBIT 6

ASSIGNMENT AND ASSUMPTION

THIS ASSIGNMENT AND ASSUMPTION (this "Assignment") is made effective as of the 29th day of December, 2003 (the "Effective Date") by and between Ethicon, Inc., a corporation organized under the laws of the State of New Jersey (hereinafter "Ethicon"), and DePuy Mitek, Inc. (formerly Innovasive Devices, Inc.), a corporation organized under the laws of the State of Massachusetts (hereinafter "DMI").

WHEREAS, Ethicon is desirous of transferring to DMI all of the assets and liabilities of Ethicon's Mitek Worldwide Division (the "Division"), and DMI is desirous of accepting such assets and assuming such liabilities.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and undertakings set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound hereby, the parties hereby agree as follows:

1. Ethicon does hereby grant, assign, convey, transfer, set over and confirm, unto DMI, its successors and assigns, forever, all the businesses, franchises, properties, and assets of every nature and description, tangible and intangible, wherever located, on the books and records of Ethicon with respect to the Division immediately prior to the Effective Date (the "Properties"), the same to include, without limiting the generality of the foregoing, those assets that are more particularly described as follows, to the extent relating to the Division:

(i) All inventories, materials, supplies, furniture, machinery, equipment, automobiles, trucks and other tangible personal property, goods and chattels, wherever located;

(ii) All right, title, and interest in, to and under all contracts, including leases (except that nothing herein contained shall be deemed to constitute the assignment of any claim against the United States of America or of any contract that is not assignable without the consent of the other party or parties thereto unless and until such consent shall have been obtained);

(iii) All right, title and interest in, to and under cash (whether on hand or in banks), notes, bonds, inventions, improvements, patents and patent applications, trademarks, copyrights, domain names, discoveries, know-how, data, accounts and bills receivable, books of account, records, agreements, licenses, claims, demands, judgments, equities and choses in action, and all other intangible property of every nature and description; and

(iv) All right, title and interest in, to and under any real estate, and any improvements and appurtenances thereon or thereto, as well as all rights and obligations appertaining thereto.

2. Ethicon hereby constitutes and appoints DMI, its successors and assigns, the true and lawful attorney or attorneys of Ethicon, with full power of substitution, for Ethicon and in its name and stead or otherwise, but on behalf and for the benefit of DMI, its successors and assigns, to demand and receive from time to time any and all the Properties hereby assigned, transferred and conveyed, and to give receipts and releases for and in respect of the same and any part thereof, and from time to time to institute and prosecute in the name of Ethicon or otherwise, but at the expense and for the benefit of DMI, its successors and assigns, any and all proceedings at law, in equity or otherwise that DMI, its successors or assigns, may deem proper in order to collect, assert or enforce any claim, right or title of any kind in or to the Properties hereby assigned, transferred and conveyed,

and to defend or compromise any and all actions, suits or proceedings in respect of any of said Properties and to do all such acts and things in relation thereto as DMI, its successors, or assigns shall deem desirable; Ethicon hereby declaring that the appointment hereby made and the powers hereby granted are coupled with an interest and are and shall be irrevocable by Ethicon in any manner or from any reason.

3. Ethicon, for itself and its successors and assigns, hereby covenants and agrees with DMI and its successors and assigns, that Ethicon and its successors and assigns will do, execute and deliver, or will cause to be done, executed and delivered, all such further acts, transfers, assignments and conveyances, powers of attorney, and assurances, for the better assuring, assigning, conveying, transferring and confirming unto DMI, its successors and assigns, all and singular the Properties hereby assigned, transferred and conveyed, as DMI or its successors or assigns shall reasonably require.

4. For the consideration aforesaid, and in consideration of the assignment, transfer and conveyance to it of the Properties, DMI hereby assumes, and agrees to pay, perform or discharge when due, as the case may be, all the indebtedness, liabilities and obligations of every kind and description, to the extent associated with the Properties or otherwise pertaining to the Division. DMI hereby covenants and agrees with Ethicon that DMI will forever indemnify and save harmless Ethicon against all the indebtedness, liabilities and obligations aforesaid hereby assumed and agreed to be paid, performed or discharged, as the case may be, by DMI and to assume and complete all pending contracts of Ethicon to the extent relating to the Division or allocated on Ethicon's books or records to the Division immediately prior to the Effective Time, and to indemnify and save harmless Ethicon and its officers, directors and stockholders from any liability under any such indebtedness, liabilities and obligations.

5. This Assignment and the covenants and agreements herein contained shall inure to the benefit of and shall bind the parties hereto and their respective successors and assigns.

IN WITNESS WHEREOF, the parties hereto have caused this Assignment to be executed in their respective corporate names as of the 29th day of December, 2003.

ETHICON, INC.

By: _____
Name: K. O'Brien
Title: Worldwide Vice President, Finance

Attest: _____
R. E. Skula, Assistant Secretary

DEPUY MITEK, INC.

By: _____
Name: H. Zauberman
Title: Vice President

Attest: _____
S. M. Rosenberg, Clerk

EXHIBIT 7

Mitek/Innovasive History

Mitek Surgical Products, Inc.

4/17/91 - Mitek Surgical Products, Inc. incorporated in Delaware.

5/13/91 - Mitek Surgical Products, Inc. merged with and into Mitek Merger Corporation with name change to Mitek Surgical Products, Inc.

Innovasive Devices, Inc.

9/30/91 – Minvasive Devices, Inc. incorporated in Massachusetts
10/8/92 – Name change from Minvasive Devices, Inc. to Innovasive Devices, Inc.
12/29/03 – Name change to Depuy Mitek, Inc. (via Restatement of Articles)

4/5/95 - Acquired by a subsidiary of Johnson & Johnson called MTS Merger Corp. MTS Merger Corp. was merged into Mitek Surgical Products, Inc. (survivor)

12/18/97 – Johnson & Johnson transferred its ownership in Mitek Surgical Products, Inc. to Ethicon Endo-Surgery, Inc.

12/29/97 - Mitek Surgical Products, Inc., Menlo Care, Inc. and Ethicon, Inc. merged with and into Johnson & Johnson Medical, Inc. (survivor) who simultaneously changed name to Ethicon, Inc.

12/30/97 - Mitek Division of Ethicon, Inc. established

12/31/98 – Innovasive Corp. a sub of Innovasive Devices, Inc. is merged with and into Innovasive Devices, Inc. (survivor).

2/11/00 – Agreement and Plan of Merger by and among Johnson & Johnson (parent), Raptor Acquisition Corp. (sub) and Innovasive Devices, Inc. (target) whereby Raptor Acquisition Corp. merged with and into Innovasive Devices, Inc.

7/2/01 - Name change of Mitek Division to Mitek Worldwide Division of Ethicon, Inc.

12/29/03 – Johnson & Johnson transfers its ownership of Innovasive Devices, Inc. to Ethicon, Inc. – (evidenced on certificate)

12/29/03 – Articles of Incorporation of Innovasive Devices, Inc. restated to reflect the new name to DePuy Mitek,Inc.

12/29/03 – Assignment and Assumption whereby Ethicon, Inc. transfers to DePuy Mitek, Inc. all assets and liabilities of Ethicon's Mitek Worldwide Division. (Former name Innovasive Devices, Inc.)

12/29/03 - Dissolution of the Mitek Worldwide Division of Ethicon, Inc.

As at 11/1/2005 - DePuy Mitek, Inc. is owned by Ethicon, Inc.

CONFIDENTIAL

EXHIBIT
Dx 6
11/2/05 MD

EXHIBIT 8

ASSIGNMENT

WHEREAS, **Ethicon, Inc.**, hereinafter referred to as the ASSIGNOR, a **Corporation** of **New Jersey**, having its principal place of business at **Route 22, Somerville, New Jersey, 08876** is the owner of certain inventions or improvements for which application for Letter Patent have been made and for which Letter Patent have been issued on May 24, 1994, as U.S Patent No. 5,314,446 entitled "Sterilized Heterogeneous Braids"(hereafter Patent Property); and

WHEREAS, DePuy Mitek, Inc., hereinafter referred to as the ASSIGNEE, a **Corporation** of **Massachusetts**, having its principal place of business at **249 Vanderbilt Avenue, Norwood, Massachusetts, 02062**, is desirous of acquiring the entire right, title and interest in and to the said Patent Property in any and all countries;

NOW, THEREFORE, for good and valuable consideration, the receipt of which is hereby acknowledged, and intending to be legally bound hereby, ASSIGNOR has sold, assigned, transferred and set over, and by these presents does hereby sell, assign, transfer and set over to said ASSIGNEE, the entire right, title and interest in and to said Patent Property and any and all continuations, divisions and renewals of and substitutes for said Patent Property and to and under any and all additional Letters Patent which may be granted on or as a result thereof in the United States and any and all other countries, and any reissue or reissues or extension or extensions of said Letters Patent, and the full right to sue for and recover damages recoverable for past infringement of the same, and for violations of provisional rights having arisen from any published application(s) for said Patent Property. ASSIGNOR further assigns to and authorizes said ASSIGNEE to file corresponding applications for Letters Patent in all countries, to be held and enjoyed by said ASSIGNEE, its successors, assigns, nominees or legal representatives, to the full end of the term or terms for which said Letters Patent respectively may be granted, reissued or extended, as fully and entirely as the same would have been held and enjoyed by ASSIGNOR had this assignment, sale and transfer not been made.

It is hereby covenanted that ASSIGNOR has full right to convey the entire interest herein assigned, and that ASSIGNOR has not executed and will not execute any agreement in conflict herewith, and ASSIGNOR further covenants and agrees that it will each time request is made and without undue delay, execute and deliver all such papers as may be necessary or desirable to perfect the title to said Patent Property in said assignee, its successors, assigns, nominees, or legal representatives, and ASSIGNOR agrees to communicate to said ASSIGNEE or to its nominee all known facts respecting said Patent Property, to testify in any legal proceedings, to sign all lawful papers to execute all disclaimers and divisional, continuing, reissue and foreign applications, to make all rightful oaths, and generally to do everything reasonably possible to aid said ASSIGNEE, its successors, assigns, nominees and legal representatives to obtain and enforce for its or their own benefit proper patent protection for said inventions or improvements in any and all countries, all at the expense, however, of said ASSIGNEE, its successors, assigns, nominees or legal representatives.

AND ASSIGNOR hereby authorizes and requests the Commissioner of Patents and Trademarks of the United States and any official of any country or countries foreign to the United States whose duty it is to issue patents on applications as aforesaid, to issue to said ASSIGNEE, as assignee of the entire right, title and interest, any and all Letters Patent for said Patent Property, including any and all Letters Patent of the United States which may be issued and granted on or as a result of any applications included in said Patent Property, in accordance with the terms of this assignment.

IN WITNESS WHEREOF, the undersigned, being properly authorized to execute this Assignment, hereunto sets their hand and seal.

Ethicon, Inc.

By: Matthew S. Goodwin
Matthew S. Goodwin

Its: _____
Assistant Secretary

Date: August 9, 2004

STATE OF New Jersey :
:SS
COUNTY OF Middlesex :

On this 9th day of August, year of 2004 before me, the undersigned officer, personally appeared Matthew S. Goodwin who acknowledged himself/herself to be the Asst Secy of Ethicon Inc., a corporation, and that he/she as such Asst. Secy, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the corporation by himself/herself as Asst. Secy.

Jacqueline S. Retkwa
Notary Public

JACQUELINE S. RETKWA
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES APRIL 10, 2006

DePuy Mitek, Inc.

By: _____
Laurence Rickles

Its: _____
Assistant Secretary

Date: August 9, 2004

STATE OF New Jersey :
: SS
COUNTY OF Middlesex :

On this 9th day of August, year of 2004, before me, the undersigned officer, personally appeared Laurence Rickles, who acknowledged himself/herself to be the Assistant Secretary of DePuy Mitek, Inc., a corporation, and that he/she as such Assistant Secretary, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the corporation by himself/herself as Assistant Secretary.

_____
Notary Public

EDNA ARNOLD
A NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES 9/27/2006

EXHIBIT 9

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

"Confidential-Non-Patent-Prosecution Counsel Only"

March 23, 2006

Comparative Suture Testing

1. Introduction

Center for Tribology, Inc., abbreviated CETR, is a privately held California corporation, located in the heart of Silicon Valley in the city of Campbell, county of Santa Clara. It was founded by Dr. Norm Gitis in November 1993 and incorporated in California in October 1994. Its main charter has been helping major corporations and universities all over the world in research, development and failure analysis of materials, coatings and lubricants for the computer peripherals (20% of revenues), semiconductor (20% of revenues), biomedical (15% of revenues) and other industries (20% of revenues), as well as for fundamental academic studies (25% of revenues). A list of its customers is attached in Appendix 1.

CETR is a multi-million-dollars corporation with two lines of business, design & sales of mechanical & tribology test equipment (90% of revenues) and testing & consulting services on mechanical & tribological properties of materials and devices (10% of revenues).

CETR is one of the largest and leading producers of mechanical and tribology testers in the world. In particular, it has supplied them to leading domestic suture manufacturers, such as Ethicon, Inc. of Johnson & Johnson and United States Surgical of Tyco Healthcare, as well as such well-known corporations as Gillette, Guidant, Medtronic, Schick, Procter & Gamble, Unilever, etc.

Dr. Norm Gitis, President of CETR, is a well-known expert on tribology testing with 30 years of experience in friction, wear and fatigue testing of materials and devices. His resume is attached in Appendices 2a – 2c.

CETR has successfully provided highest quality laboratory test data in several lawsuits, including most recently between Alaska Airlines, Boeing, and families of victims of the Alaska flight 261 (related to the reliability of a jack-screw/nut assembly on Boeing airplanes and a plane crash in 2000), between American Airlines, Sabre Travel Network and Western Digital (related to the reliability of computer disk drives used for travel reservations), and between Boston Scientific and US Justice Department (related to the quality of implantable cardiovascular stents). It has been charging $ 2,500 per day or $ 10,000 per week for its regular lab testing services and double prices for priority urgent services.

Dr. Gitis has successfully testified in several depositions, most recently in a lawsuit between Seagate Technology and Cornice, Inc. related to the intellectual property on the mechanical design of portable magnetic disk drives. He has also given successful testimonies at several trials, most recently in lawsuits between Swiss Air, Interactive Flight Technology, Avnet and other parties (related to the reliability of computerized on-demand in-flight video system and a crash of Swiss flight 111) in the court of Arizona and between Iomega and Nomai (related to the reliability of Zip high-density floppy-drives) in the Higher Court of

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United Kingdom, courts of Amsterdam, Dusseldorf, etc. He has been charging $ 350 per hour plus trip expenses for his consulting and expert witnessing services.

2. Project Goal

At the end of February 2006 CETR was requested by a law firm of Dickstein, Shapiro, Morin & Oshinsky, LLP (located at 2101 L Street NW, Washington, DC 20037) and its technical expert Dr. Debi Mukherjee to perform comparative mechanical and tribological testing of two types of FiberWire surgical sutures, coated and uncoated.

They requested the following parameters be tested: i) pliability/bendability, ii) knot tie-down/run-down, iii) knot security, iv) chatter, v) coefficient of friction, vi) tissue drag, vii) microscopy examination.

We have been told that this project is related to a patent infringement lawsuit between DePuy Mitek, a Johnson & Johnson company and Arthrex, the latter being the client of this law firm. Any details of the lawsuit have been neither requested by CETR nor provided to CETR.

3. Suture Samples

In the beginning of March 2006 CETR received via FedEx two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated. Each spool contained approximately 20 m of suture. Two CETR employees Dr. Norm Gitis and Mr. Michael Vinogradov examined the spools of sutures and found them to be apparently brand new.

Upon agreement with the law firm and Dr. Mukherjee, before conducting any tests, we sent both the spools of sutures for ETO sterilization to a reputable sterilization lab Sterile Systems, Division of Medtronic Inc. (located at 520 Watson S.W., Grand Rapids, MI 49504). The same Mr. Michael Vinogradov handled the sutures before the shipment and after receiving them back. Both shipments to and from Sterile Systems were performed via FedEx.

Upon receiving back the sterilized sutures, we handled them only and always with clean-room gloves. We cut about 3 m of each of the coated and uncoated sutures and shipped by FedEx to a surgeon expert, as requested by the law firm. The rest of the spools were utilized in our tests described below.

4. Set Of Test Procedures

Based on the CETR experience with its suture-tester customers Ethicon (New Jersey) and US Surgical (Connecticut), its general expertise in mechanical & tribology testing and familiarity with the relevant literature, as well as on the suggestions of the law firm, CETR has proposed a suit of test procedures for the requested tests, that was approved by the law firm's technical expert Dr. Mukherjee and then performed by CETR in mid-March, 2006.

5. Pliability Tests

The experimental procedure, based on the published work of Rodeheaver et al. [1], was as follows.

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Suture of 50 mm in length and 0.65 mm in diameter was clamped between the force sensor and the lower specimen holder as shown in fig. 1. The suture was preloaded with a tension of 0.5 Kg (5 N). Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kg/sec. Force and elongation data were continuously monitored and recorded. The strain in the suture was calculated as the ratio of elongation to the initial length of 50 mm. The force-strain plots like the one shown in fig. 2 were made and their slopes were measured. Modulus of elasticity (E) was then calculated by dividing the slope with the cross-sectional area of the suture. Area moment of inertia (I) was calculated assuming a circular cross-sectional area. Stiffness was then calculated as a product of the modulus of elasticity and the area moment of inertia of the suture:

$$K = E*I$$

where
K – Stiffness,
E - Modulus of elasticity - Slope of the force-strain graph / cross-sectional area of the suture

I - Area moment of inertia - $\frac{\pi * D^4}{64}$ where D - diameter of the suture (0.65 mm)

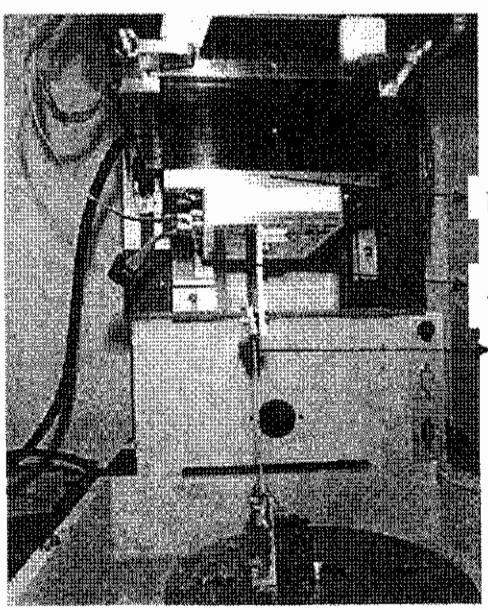

Figure 1. Test set up for pliability testing

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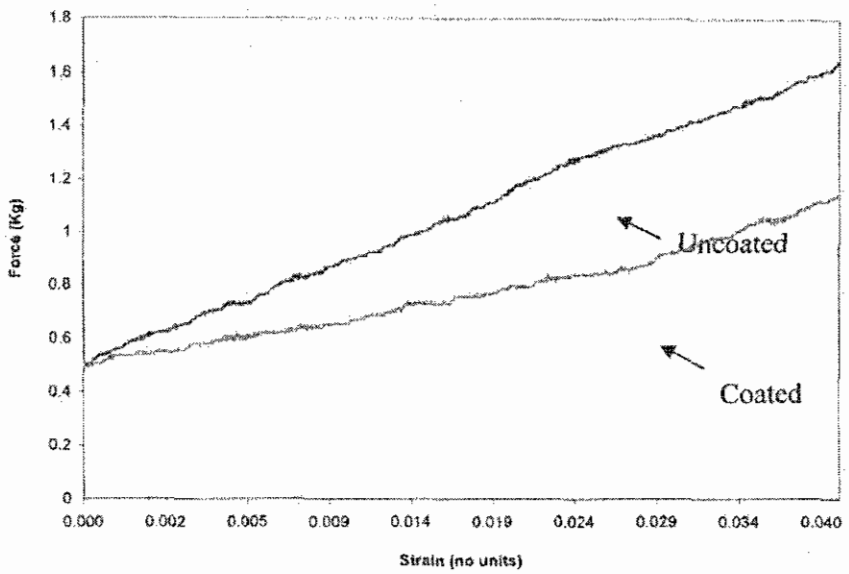

Figure 2. Typical force-strain data for coated and uncoated sutures during pliability tests

The stiffness values as calculated in the above described procedure are summarized in the Table 1.

Table 1. Pliability test data

Exp #	Stiffness (*E10-7 kg x m^2)	
	Coated Suture	Uncoated Suture
1	6.51	10.07
2	7.53	9.73
3	5.98	11.3
4	6.44	11.3
5	4.95	8.29
6	5.67	8.00
7	5.98	9.61
8	5.41	10.6
Average	6.06 ± 1.29	9.93 ± 1.66

The stiffness of the coated sutures was found to be lower than that of the uncoated ones. This suggests that the coated sutures have higher pliability and thus facilitate better handling during surgical use. The test data corresponds well to the data reported by Rodeheaver et al [1].

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6. Knot Slippage Strength Tests

The knot slippage strength tests were conducted to evaluate the knot security offered by each suture. The experimental procedure was carried out based on previous works in the literature [2, 3]. A loop of the suture was formed by tying a 'square knot' as shown in fig 3 [4] around a cylinder of 2.5 cm diameter. The loop thus formed was slipped off the cylinder and soaked in 0.9% weight/volume sodium chloride for 1 minute to closely represent the real environment. The soaked loop was then placed around 2 parallel brass rods of 5 mm diameter, which were mounted onto the UMT-2 machine as shown in fig. 4. A pre-load of 1 N was applied to the loop. The parallel rods were then pulled apart at a constant velocity of 1 mm/sec. The force was continuously monitored and recorded during the experiment. The force when the knot starts slipping was noted as the knot slippage force. The rods continued to be pulled apart until either the knot got untied or a slippage of 3 mm occurred. The force at that instant gives the knot failure force.

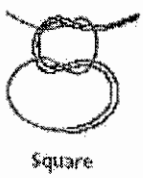

Figure. 3 'Square knot' used for the knot slippage strength tets

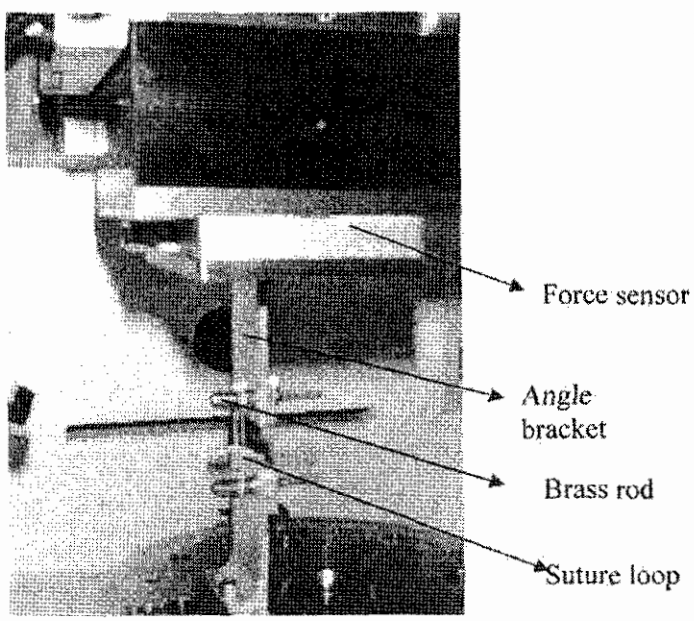

Figure 4. Test set up for knot slippage strength measurement

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The typical force response curves as recorded during the experiments are presented in the fig. 5 below.

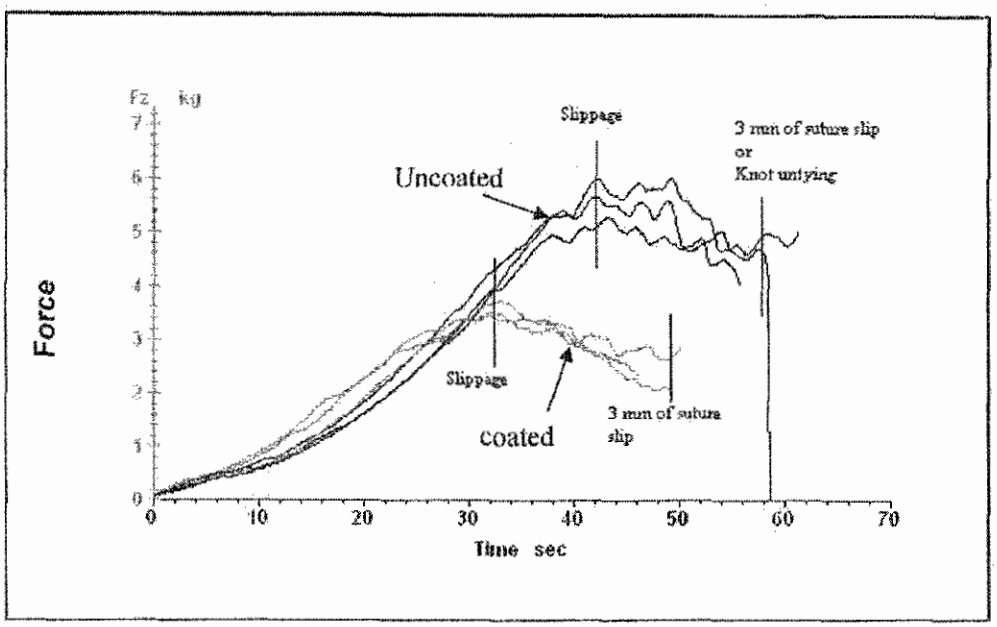

Figure 5. Typical data for force at slippage and knot failure for coated and uncoated sutures

The knot strength values as determined from the curves are summarized in the Table 2 below.

Table 2. Knot strength data for coated and uncoated sutures

Exp #	Knot strength (kg)			
	at slippage		at knot failure	
	Coated	Uncoated	Coated	Uncoated
1	3.52	5.33	3.06	4.09
2	2.36	4.97	2.03	4.09
3	3.46	4.80	3.15	2.42
4	4.25	6.04	2.07	2.98
5	3.74	4.70	2.40	3.53
6	2.43	5.36	2.77	4.79
7	3.47	4.86	2.09	3.45
8	3.27	5.10	2.64	3.90
Average	3.31± 0.95	5.14 ± 0.67	2.52 ± 0.56	3.36 ± 1.19

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From the above data it can be concluded that the knots tied using the coated sutures slipped and failed at lower forces when compared to the knots tied using uncoated sutures. The experimental data compare well with the data reported in the previous works [2, 3].

7. Knot Run-down Tests

The suture was tied with a 'half hitch knot' as shown in fig. 6 [4] around a supplemental cylinder with a 2.5 cm diameter. The loop thus formed was then slipped off the supplemental cylinder and placed on the lower brass rod of the UMT-2 testing machine. The knot was then subjected to running-down by pulling at a constant speed of 1.5 mm/sec on the longer free end in the testing machine as shown in fig. 7. The test procedure was based on the description provided in the literature [5]. The pulling force was continuously recorded as the knot traveled down the suture. Chatter or variation in knot run-down force was also noted.

Figure 6. Half-hitch tied for the knot run-down tests

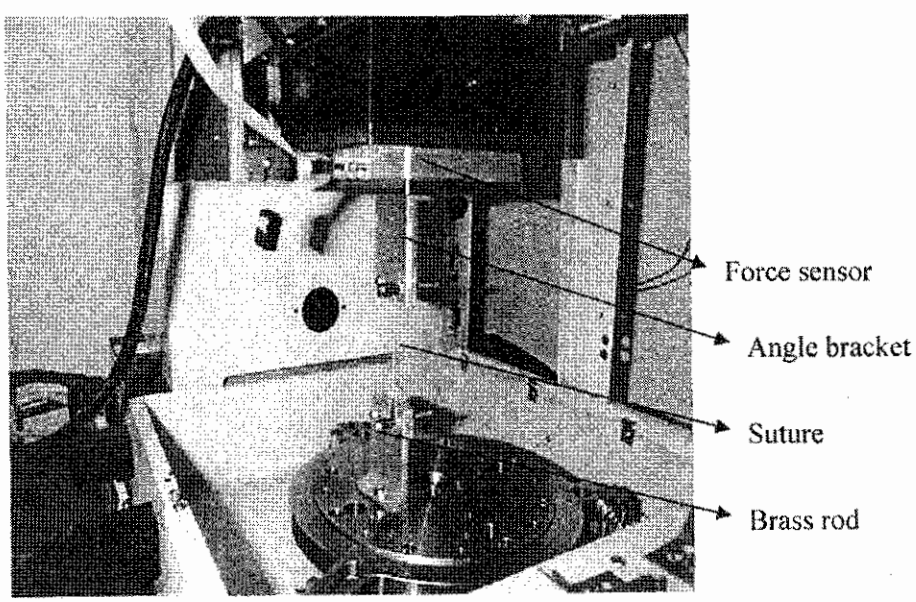

Figure 7. Test set up for the knot run-down test

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The typical pulling force data from the tests performed on coated and uncoated sutures plotted versus time is shown in fig. 8 below:

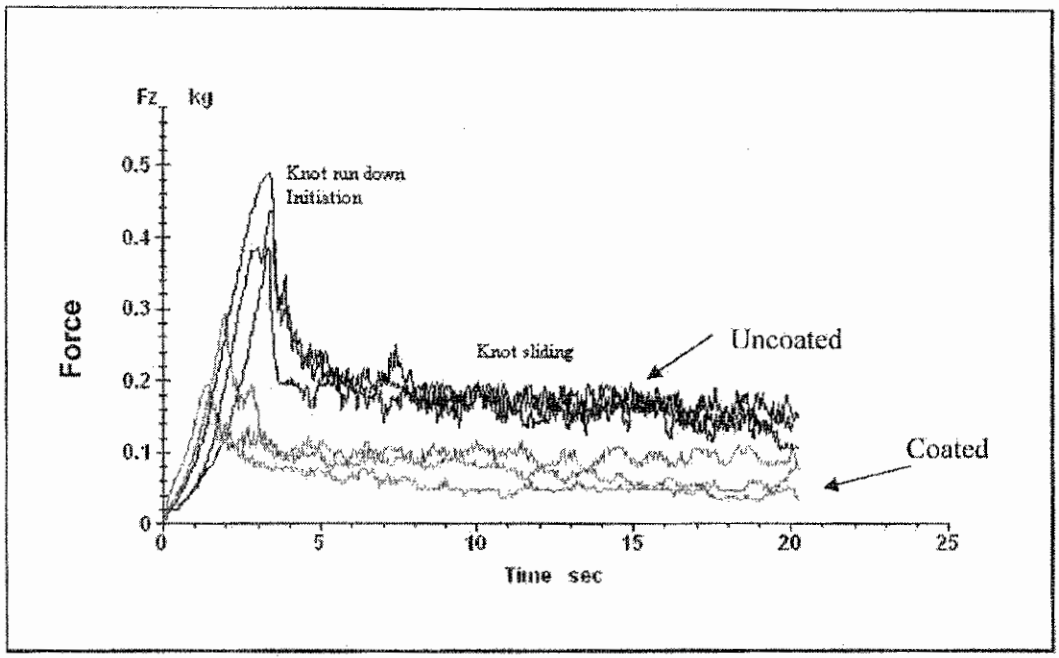

Figure 8. Force versus time for coated and uncoated sutures during knot run-down experiments

The force when the knot begins to slide over the suture was noted from the pulling force data. This gives the run-down force. The run-down force values as measured from the test data are tabulated in the Table. 3 below:

Table 3. Knot run-down test data

Exp #	Run-down force (kg)	
	Coated suture	Uncoated suture
1	0.28	0.39
2	0.20	0.54
3	0.26	0.42
4	0.22	0.49
6	0.18	0.44
7	0.19	0.28
8	0.21	0.26
average	0.22 ± 0.05	0.40 ± 0.14

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As can be seen from the above result, the coated sutures had lower run-down force when compared to the uncoated sutures.

8. Friction tests

The schematic of suture-on-suture testing set-up is shown in the fig. 9 below.

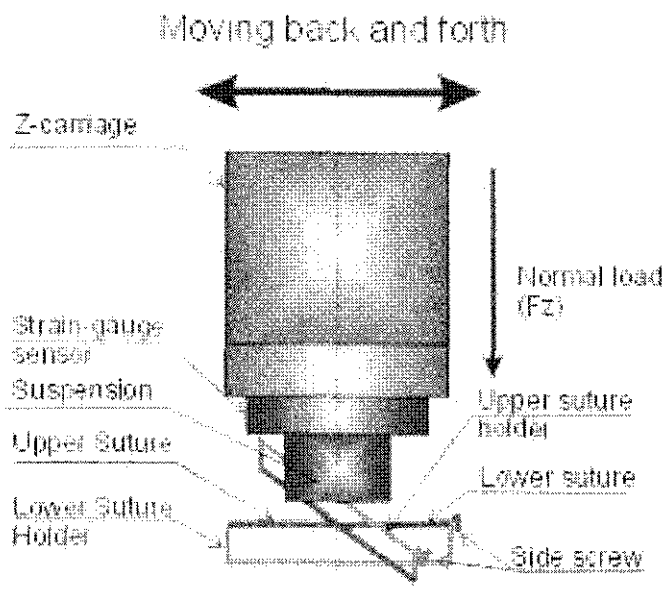

Figure 9. Test schematic for measuring suture-on-suture friction

A sample of suture was mounted and tensioned on the upper sample holder and another sample of the same suture was mounted and tensioned on the lower sample holder. The tension of both the sutures was adjusted using side screws to ensure constant tension for each suture, as shown in fig. 10. The upper suture was moved on the lower one back and forth with a reciprocating length of 3 mm at a frequency of 0.5 Hz under a constant normal load of 2 N (0.2 kg) for 200 seconds. A close-loop feedback loading mechanism ensured a constant normal force.

Both the applied vertical load and friction (shear) response force were continuously monitored and recorded during the tests.

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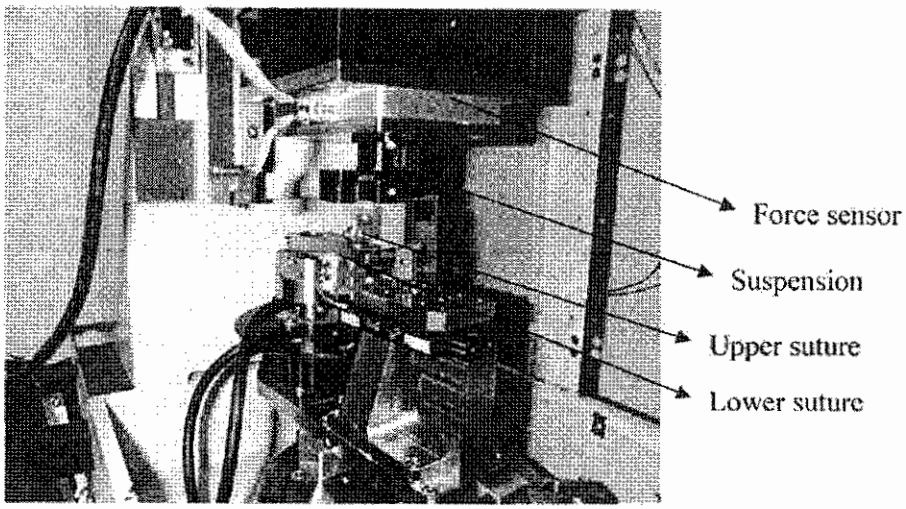

Figure 10. Set up of suture-on-suture friction tests

The coefficient of friction curves as recorded during the reciprocating tests are presented in fig. 11 below. The uncoated sutures had higher average coefficient of friction. The numerical data from the tests are noted and summarized in table. 4

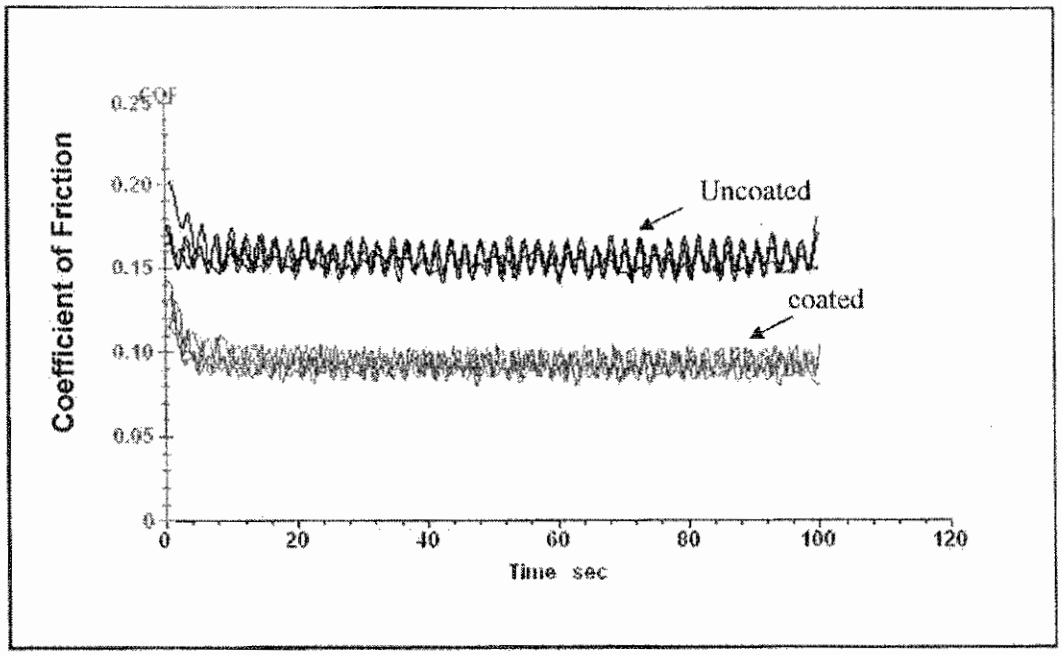

Figure 11. Typical Coefficient of Friction curves for Coated and Uncoated Sutures

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Table 4: Average coefficient of friction data from suture-on-suture tests

Exp #	Coefficient of Friction	
	Coated suture	Uncoated suture
1	0.09	0.15
2	0.10	0.17
3	0.08	0.16
4	0.10	0.16
5	0.09	0.16
6	0.09	0.16
7	0.09	0.17
8	0.10	0.17
Average	0.09 ± 0.01	0.16 ± 0.01

From the above results, it can be seen that the coated sutures have lower coefficient of friction when compared to the uncoated sutures. This result correlates well with the run-down force data in the previous section. The average coefficient of friction data is similar to the previous data [1, 6].

9. Chatter Data

Chatter is termed as the variation in friction during knot run-down and/or reciprocating friction tests. These variations are due to stick-slip process between the interacting suture surfaces when the knot is tied-down [5]. The difference between the maximum and the minimum friction coefficients, or amplitude of frictional auto-oscillations, is the measure of the chatter. Chatter data measured from both the knot run-down and the suture-on-suture friction tests are summarized in the table 5 below.

Table 5: Chatter data from knot run-down and suture-on-suture tests

Test #	Chatter data	
	Coated suture	Uncoated suture
1	0.009	0.013
2	0.009	0.017
3	0.008	0.013
4	0.008	0.013
5	0.010	0.012
6	0.012	0.011
7	0.008	0.014
8	0.010	0.019
average	0.009 ± 0.001	0.014 ± 0.003

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The chatter was higher for the uncoated sutures when compared to the coated ones. This result strengthens the conclusion from the previous results that coated sutures provide greater ease of handling during surgical use.

10. Tissue Drag Tests

The frictional force encountered during the passage of the suture through a tissue is termed as tissue drag. A 20-mm length of suture was pulled through a piece of leather at a constant rate of 1 mm/sec, while continuously recording the pulling force. The test procedure is based on the description provided in the previous works [7]. The leather piece was held in position using fixtures as shown in fig. 12. Two types of tests were performed: dragging the suture through the hole made with a needle and dragging the suture between two tightly clamped pieces of leather. In both cases, the upper end of the suture was attached to the UMT upper bracket providing the well-controlled motorized dragging action. The average drag force measured in both types of experiments was identical.

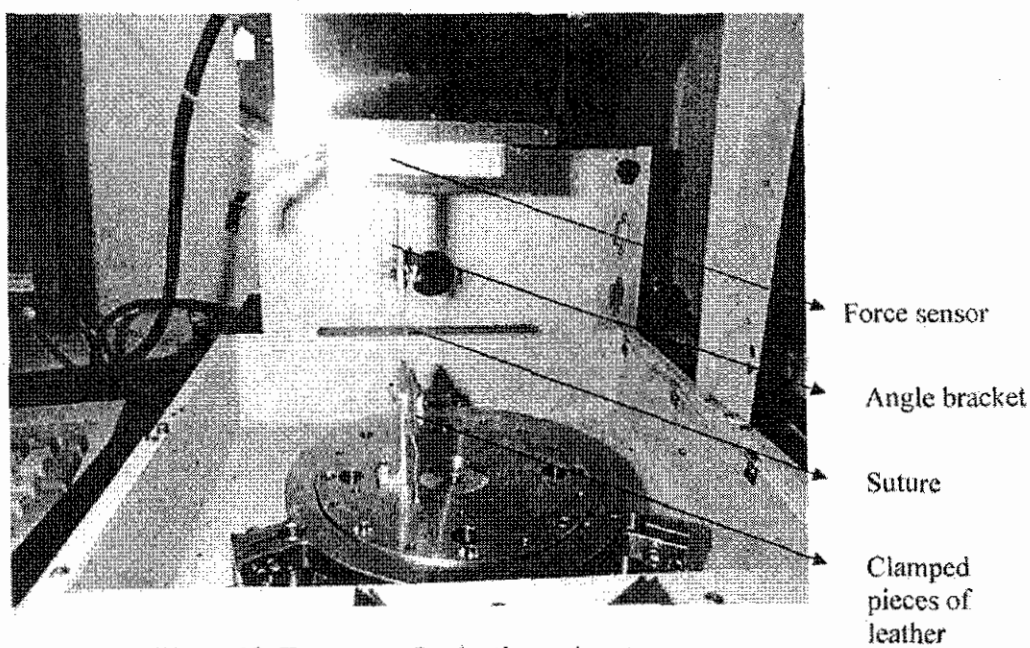

Figure 12. Test set up for the tissue drag test

Fig. 13 presents the force required to pull the coated and uncoated sutures. The highest force recorded gives a measure of the static drag force that was necessary to overcome in order to initiate the suture motion through the leather. The dynamic drag force was measured during the motion of the suture. The average static and dynamic drag forces are summarized in Table 6. The data are comparable to the previously reported results [1].

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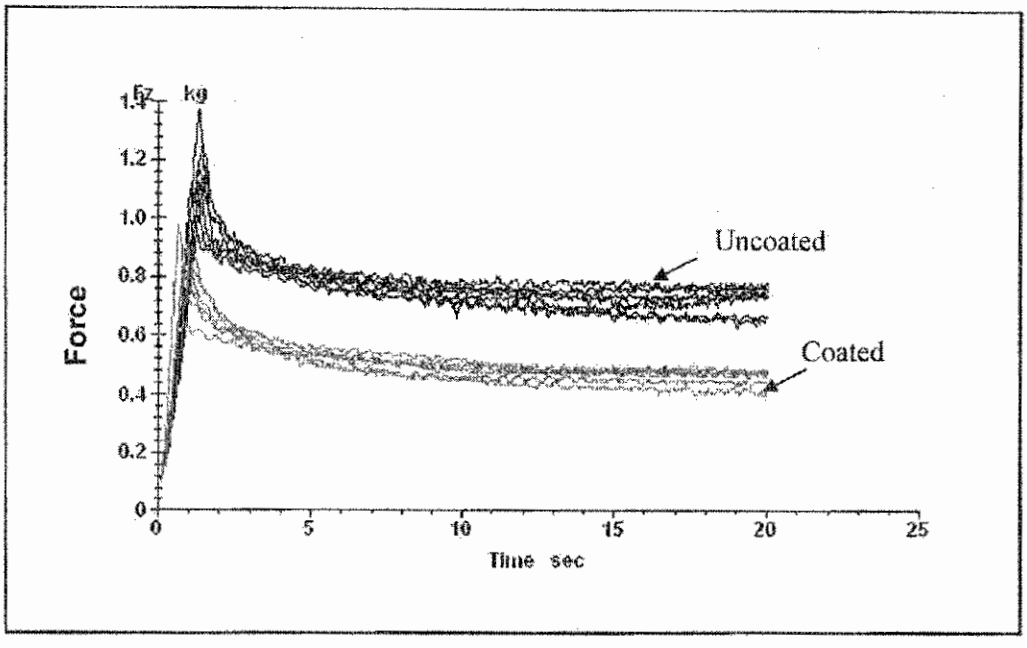

Figure 13. Typical force curves for coated and uncoated sutures.

Table 6. Drag force from the tissue drag tests

Exp #	Drag force (kg)			
	Static		Dynamic	
	Coated suture	Uncoated suture	Coated suture	Uncoated suture
1	1.10	1.15	0.55	0.74
2	0.86	1.20	0.52	0.78
3	0.71	1.19	0.41	0.84
4	0.68	1.39	0.46	0.91
5	0.97	1.10	0.46	0.85
6	1.11	1.19	0.58	0.64
7	0.90	1.13	0.51	0.77
8	0.92	1.13	0.50	0.72
Average	0.91 ± 0.20	1.18 ± 0.15	0.50 ± 0.11	0.78 ± 0.14

11. Microscopy Data

We have attempted to stud y the structure of the sutures with a digital optical microscope, attached to the same UMT tester, but the structure was undistinguishable. So, we utilized

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laboratory imaging services of a reputable local analytical lab AMER in Sunnyvale, California. Dr. Gitis brought samples of the uncoated and coated sutures to AMER and was present there all the time while their lab engineer Tony Lin performed SEM (scanning electron microscopy) imaging.

The obtained images are presented below in figures 14 and 15.

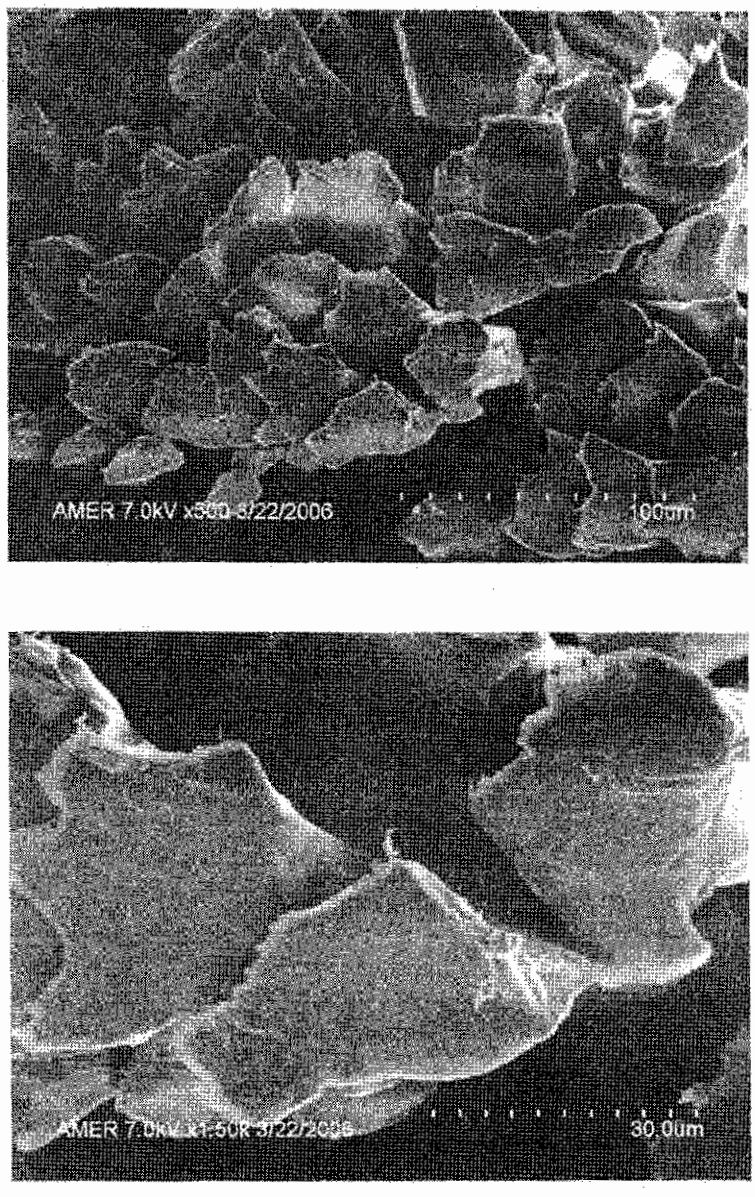

Figure 14. SEM Photos of the Coated Suture

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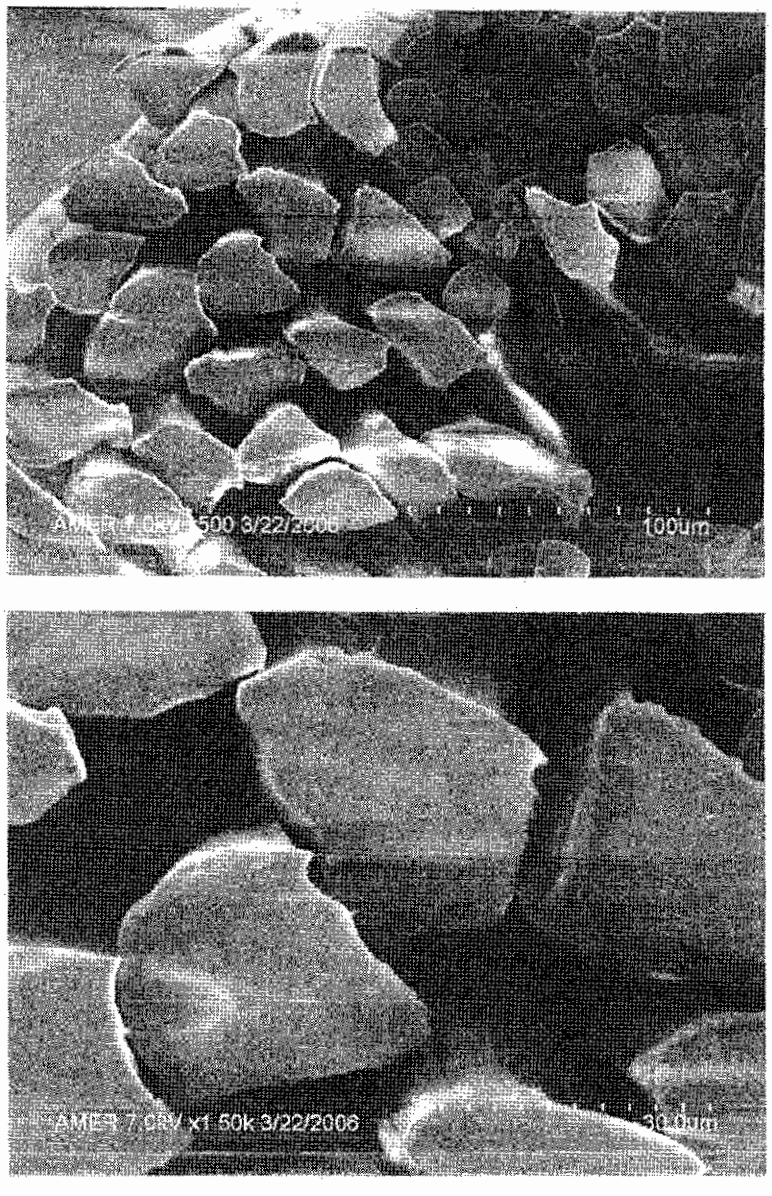

Figure 15. SEM Photos of Uncoated Sutures

12. Statistical Significance of Test Data

We used a common t-distribution statistical analysis, assuming the test data to be normally distributed The t-analysis assesses whether the means of two data groups are statistically

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different from each other. Then the test statistic (t-value) is calculated as [8, 9]:

$$t = \frac{Xu - Xc}{\sqrt{\frac{Vc}{Nc} + \frac{Vu}{Nu}}}$$

where X_c and V_c - mean and variance, correspondingly, of data for coated suture,
X_u and V_u - mean and variance, correspondingly, of data for uncoated suture,
N_c and N_u - number of tests for coated and uncoated sutures, correspondingly (N = 8).

The calculated t-values for all our test data are presented in Table 7 below.

Table 7. Comparison of t-values for data significance

Test	Coated		Uncoated		Experimental "t"-value	"T" threshold
	Xc	Vc	Xu	Vu	t	T
Stiffness	6.06 E-6	6.17 E -13	9.93 E-6	1.6 E -12	7.35	1.76
Slippage Strength	3.31	0.41	5.14	0.19	6.72	1.76
Untie Strength	2.52	0.2	3.66	0.54	3.72	1.76
Run-down Force	0.22	0.001	0.4	0.01	4.62	1.76
Friction	0.09	3.58 E -5	0.16	5.66 E -5	20.27	1.76
Chatter	0.009	1.58 E -6	0.014	6.91 E -6	4.63	1.76
Static drag	0.91	0.025	1.18	0.008	4.29	1.76
Dynamic drag	0.5	0.003	0.78	0.007	7.91	1.76

To make a conclusion that the difference between groups of data is statistically significant, the t-value should be larger when compared to a T-threshold calculated based on the degrees of freedom of the distribution and an error level. Degrees of freedom is calculated as [8]: DoF =

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$N_C + N_U - 2 = 14$. An error level of 0.05 (5%) is most commonly used. Based on the DoF and error level, the *T-threshold* is found from a standard t-distribution table [8, 9] to be $T = 1.76$.

As seen from the Table 7, the computed t-values of test data are much greater than the threshold T level, which allows us to conclude that the observed differences between coated and uncoated sutures are statistically significant.

Norma Gitis

Dr. Norma Gitis
President, Center for Tribology, Inc.
Chairman, STLE Technical Committee on Tribotesting

References:

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EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

DEPUY MITEK INC., a Massachusetts Corporation, Plaintiff,	:	
vs.	:	Civil Action No.
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, Defendants.	:	04-12457

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:15 a.m., at the law offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Dawn A. Jaques, Certified Shorthand Reporter and Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

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A. Yes.
Q. And on the graph that's on the first page of Exhibit 393, there is eight graphs present, eight lines presented. Do you see that?
A. Yes.
Q. And they're labeled Coated 1 through 8. Do you see that?
A. Yes.
Q. Do the Coated 1 through 8 that are in there correspond to the Experiment No. 1 through 8 that are in the pliability test data chart?
A. Yes.
Q. Okay. Now, if we look at 394, the first column is FZ in kilograms. Do you see that?
A. Yes.
Q. What force is that?
A. Vertical force.
Q. That's the force that's being applied to the specimen placed under tension?
A. Yes.
Q. The second column is time and seconds; is that right?
A. Yes.
Q. The third column is Z in millimeters, right?

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A. That's correct.
Q. What is Z?
A. Displacement in millimeters.
Q. Vertical displacement, so it's how much the specimen is being stretched, right?
A. Yes.
Q. Okay. The fourth column is ZABS, Z-A-B-S; is that right?
A. Yes.
Q. What is ZABS?
A. I don't remember.
Q. Don't know?
A. I don't remember.
Q. Okay. The fifth column is Strain. Do you see that?
A. Yes.
Q. What is that?
A. Strain is the ratio of the relative displacement over the initial position.
Q. So this strain --
A. Elongation over -- strain is defined as relative elongation, elongation over the length.
Q. So is it correct that the strain is the distance measured with the Z parameter divided by the length?

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A. Yes.
Q. So at the first instance, the length was measured to be 50 millimeters. That was the gauge length you used, right?
A. Yes.
Q. So the time -- at the first entry, let's say, the strain --
A. No change.
Q. There was no change.
A. Zero change. Zero divided by any number gives zero.
Q. Zero. Second entry says -- for the Z column is 24.8735, right?
A. Yeah.
Q. So the strain then would be 24.8735 divided by 50, plus 24.8735 for that data point?
A. Yeah.
Q. For the next data point, it would be 24 point -- the strain would be 24.8735 divided by 50, plus 24.8735?
A. Yes.
Q. So it keeps on doing that?
A. Yes, all the time.
Q. Okay. And you said in your task, if you go back to your report on page 3 at the top, you

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said that suture was tested -- was preloaded with a tension of .5 kilograms, 5 newtons, right?
A. Yes.
Q. How did you arrive at that parameter?
A. Why did we choose this parameter, because we followed the literature recommendations by Dr. Rodeheaver and by Ethicon.
Q. Did one of those documents actually specify a 5 newton preload?
A. I think so.
Q. What happens if they didn't?
A. I would be surprised.
Q. If they didn't, would you know where it came from?
A. I am under the impression that it came from the literature.
(DePuy Mitek Exhibit No. 395 was marked for identification.)
BY MR. BONELLA:
Q. Let me show you what's been marked as DePuy Mitek Exhibit 395. It's Dr. Mukherjee's response of expert report. I'd like to ask you to turn to Exhibit -- I'm going to turn to Exhibit 13.
Exhibit 13 to that report is --

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holders or these sensors or whatever, but I cannot speculate what causes the difference between uncoated and coated, because as we discussed, I only know labels, coated and uncoated, so I cannot speculate what causes their differences. Erich, you need a new printer.

(DePuy Mitek Exhibit No. 404 was marked for identification.)

BY MR. BONELLA:

Q I'm going to show you the next exhibit, Exhibit 404, which I believe is the knot strength test data and curves for the uncoated samples. I ask you to verify that.

A Uncoated, yes.

MR. TAMBURO: You want him to look through that 8 inches worth of documents?

BY MR. BONELLA:

Q Do you know? Can you just look at the --

A Yeah, I see it. It's uncoated, yeah.

Q Is that the data for the non-slippage test?

A Yes.

(DePuy Mitek Exhibit No. 405 was marked for identification.)

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BY MR. BONELLA:

Q Is Exhibit 405 the graphs and data for the coated non-slippage test?

A Yes.

Q Okay. Let's take, for example, the coated. Turn to the first part. This is where you were putting the preload on, right? The first part of the data should be where you put the preload on; is that right?

A Yes.

Q Okay. There is, for example, sample 1 we'll use an example, there's five columns, right?

A Yes.

Q First column is F sub X. What is that?

A FX is horizontal force in X direction.

Q Force in X direction. If we're looking at Figure 7, your set-up, which is the X direction?

A X direction is parallel to the paper.

Q Parallel to the paper. That's not specific.

A I'm sorry, what are you looking --

Q Figure 7, your test set-up. That's right, you got it.

A No, you said Figure 7.

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Q Oh, do I have the wrong one? I'm sorry, I have the wrong one. Figure 4.

Okay, so where was the X direction for Figure 4?

A Left-right direction within the plane of the paper.

Q I'm having a hard time understanding because there's two planes to the paper. Well, there's one plane, but there's two directions. There's a --

A I'm sorry, do you see -- how to define X. If you see a force sensor, it has some kind of lengths, so X is along the length of the force sensor.

Q Okay. So would the force X be into the diameter of the brass rod?

A Yes.

Q Next column is F sub Z. What is that?

A It's a vertical force.

Q That's the tension force that you're measuring?

A The tension force.

Q That you measure to get the results?

A Yes.

Q T is time and seconds, right?

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A Yes.

Q Z is what?

A Z is vertical displacement.

Q Okay. So that's what you're looking at to determine slippage?

A Yes.

Q And the last column is F sub F. Do you see that?

A Yes.

Q Is that the force in the Y direction?

A Actually, that's friction coefficient.

Q That's friction coefficient?

A Yeah.

Q In kilograms?

A Okay, I am confused.

Q Weren't you trying to keep the forces in the X direction and the Y direction the same?

A No, FY would say FY. So I'm sorry, I confused. I don't remember. I can find it out and let you know. I don't remember specifically.

Q You don't know what FF is? Look FX and FF columns, if you look at those --

A Yes. They seem to be of certainly equal --

Q Except for this sample they're not.

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labeled brass rod is?
A That's correct.
Q The knot was then subject to running down by pulling at a constant speed of one and-a-half millimeters per second on the longer free end in the testing machine as shown in Figure 7, right?
A Yes. The free end was like upper end, and the loop was like the lower end of the suture on Figure 7.
Q The loop is around the rod, right?
A Yes.
Q And then there's two ends?
A Right.
Q One was -- and you pulled on one end?
A Yeah, the longer end.
Q Okay. And the longer end, how did you attach that to something to pull on it?
A How we attached it to the -- to the upper specimen, with the same angle bracket as was shown in pliability test and knot strength test.
Q It doesn't show it.
A As you said, you can call it bolt and nut.
Q I'm sorry.

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A As you said previously, you can call it bolt and nut, how we clamp the suture.
Q I don't understand what you just said.
A Okay.
Q I don't understand what you're saying.
A Earlier when I described our clamp to clamp the suture, you asked me whether you can call it bolt and nut, and I said yes.
Q Okay. I see in the Figure 7, test set-up for the knot run-down, there's a brass rod in the upper fixture.
A Yes.
Q What was that used for? Looks like the suture is looped around it, no?
A Yes. Maybe it's wrong photo. It's photo from Figure 4. Maybe it's the right photo for the upper attachment is the same as in Figure 1.
Q Wait a minute, I'm confused now. Are you saying Figure 7 may not be the knot run-down test?
A Figure 7 is -- no, no. It's correct. Figure 7 is a knot run-down test. The loop was formed on the separate supplemental cylinder, was then transferred on the brass -- on the lower

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brass rod.
Q Yes.
A And then the free -- longer free end was just attached to the upper rod.
Q Attached to the upper brass rod?
A Yes.
Q How was it attached to the upper brass rod?
A I don't remember.
Q Was it tied in a knot?
A I don't remember. Most likely it was tied in a knot.
Q How about the lower -- how about the other end, what happened to the other end of the suture? What did you do with that?
A I believe it was cut like in all the referenced literature.
Q What do you mean cut? There's two ends of the suture that are in the half hitch, and one you said goes up --
A The longer ones, the free one, goes on the upper rod.
Q Okay. What happens to the lower one? What happens to the other end?
A I don't remember. We didn't describe

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here, and I don't remember.
Q Well, how is the knot running down? I mean, what's holding the other end? Something's got to hold the other end, right --
A Right.
Q -- if it's a run-down test.
A Right. Sorry, I don't remember.
Q So you can't exactly tell me how this test was done?
A I have to think about it. I don't remember.
Q Okay. How many kilograms in a newton?
A One kilogram is 9.8 newton.
Q Let me show you the first page of Exhibit 404 back at the knot slippage strength test. I'm going to shift gears on you here. There's a line at the 10-second point?
A Yes.
Q What is that line for, that vertical line?
A I do not remember.
Q Is someone looking at the slope before 10 seconds?
A I do not remember.
Q So in this test, the -- I guess you

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don't remember. Anyway, the constant speed at the knot run-down, 1.5 millimeters per second, should be reflected in the data, right?
A Yes.
Q If you go to the table of the data results, see how Sample 1, coated, was .28, and sample 7, uncoated, was .28?
A Yes.
Q How do you explain that they were the same?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: I don't have any explanation.
BY MR. BONELLA:
Q And sample 3 was .26 and sample -- I'm sorry, sample 3, coated, was .26, and sample 8, uncoated, was .26. Can you explain that?
MR. TAMBURO: Same objection.
THE WITNESS: No.
BY MR. BONELLA:
Q Okay. The data where knot run-down force that's in the table, how did you generate those values?
A We calculated it as a force at the

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moment when knot begins to slide down.
Q And how do you know when the knot begins to slide down?
A You look in the Figure 8, and you can clearly see that for as long as knot is intact, like in previous test, force goes up with the increase in time/distance.
As soon as force stops increasing with time, it means that knot started to run down.
Q Did you pick the peak of the curves, or was there an algorithm?
A Peak.
Q Peak?
A Yes.
Q You say that you also noted chatter variation, and knot run-down force was also noted.
Do you see that?
A Yes.
Q Did you determine chatter from this test that present the chatter results?
A When we presented the chatter in -- when we presented chatter in Table 5, it was kind of average of the amplitude in Figure 11 and amplitude in Figure 8.
Q It was the average of the amplitudes?

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A I'm sorry, it was average of two chatters, right? Chatter in Figure 11 and chatter in Figure 8.
Q Okay, I'll come back to that then when we get to chatter.
(DePuy Mitek Exhibit Nos. 406 and 407 were marked for identification.)
BY MR. BONELLA:
Q I'll show you Exhibit 406. I believe this is the printout of the uncoated data from the knot run-down test.
I'll show you Exhibit 407. I believe this is the coated data from the knot run-down test. Does that look right?
A It looks correct.
Q Let's look at 407 for a minute, the coated values. If you look at the data under the first sample -- I guess for all the data that we look at, does the sample No. 1 always correspond with the Experiment No. 1 value in your charts?
A Yes.
Q The first column is F sub X. What is that?
A Again, it's the lateral force in X direction.

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Q Which is the X direction?
A As we discussed, it's longitudinal of the force sensor -- along the longitudinal axis of the force sensor.
Q So it's into the brass rods on Figure 7?
A Yes.
Q And F sub Z?
A Is vertical force.
Q T is time and seconds?
A Time. Z is displacement. And, again, I don't remember what is sub F.
Q So in this -- once the -- was a preload done in this?
A It doesn't specify preload.
Q How about -- so a preload wasn't done?
A Correct.
Q Did you soak the sutures first?
A It doesn't specify, so we did not.
Q Now, for the knot run-down curves, can you -- before the onset of the run-down initiation, so before the peak is reached, can you use that data to determine pliability as you did for Table 1?
A It would give you a big, big error.
Q Why?

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A Because of the same reasons as we discussed last time. Because if there is a loop, it measures friction because it's combination of friction and elastic properties. Because there was no substantial preload, you can really use it for pliability.
Q The duration in this, is that the time that the test took?
A Yes.
Q And the count, what is that?
A As last time, it's data rate, data frequency, how many data points. This count is higher than in test one because we needed to catch the peak, so we had higher frequency of data to catch the weighted peak of the run-down.
Q If you look at sample 7 in Exhibit 407 --
A 7, Exhibit 407, yes.
Q Coated, sample 7, it looks like it had the highest force?
A Yes.
Q Okay. And it was, I don't know, roughly .28, .29?
A Yes.
Q If we go to your data for knot run-down

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test, sample 7 is 0.19 for coated.
A Yes.
Q How do you explain that?
A No explanation.
Q The next test, the friction test.
(A discussion was held off the record.)
MR. TAMBURO: Do you mind taking a 2-minute break?
MR. BONELLA: No.
THE VIDEOGRAPHER: This is the end of Tape 3. Off the record at 3:26:09.
(A break was taken.)
THE VIDEOGRAPHER: This is the beginning of Tape 4 in the deposition of Dr. Norm V. Gitis. On the record at 3:35:22.
BY MR. BONELLA:
Q Dr. Gitis, is the Table 2 in Exhibit 382 of knot strength any different than the knot strength data that you presented in Exhibit 381?
A No, it's the same.
Q I'd like to show you, this is going back to this knot strength slippage test for a minute.
A Yes.
Q That was done, according to your report, at a constant speed of 1.5 millimeters per second,

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right?
A 1 millimeter per second, yes.
Q 1 or 1.5?
A For slippage, 1; for run-down, 1.5.
Q Sorry. Slippage was 1 millimeter per second?
A Right.
Q Okay. Let's look at the -- this is the slippage data, Exhibit 405, with a coated suture, right? If you look --
A Yes.
Q Look at this page here, and you look at time equals 4 seconds for sample 2 -- sample 1.
A Okay.
Q Sample 1, time of 4.002 -- wait.
A Yeah, 4 seconds.
Q For sample 1, the coated, time of 4.002 seconds, Z at a value of 115 --
A .33.
Q -- .33345, correct?
A Yes.
Q So if we're going at a constant velocity of 1 millimeter per second, Z is in millimeters, at 5 seconds we should have 116.3345, right, for Z?

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A Yes.
Q Let's mark the page we just looked at as Exhibit 408.
(DePuy Mitek Exhibit No. 408 was marked for identification.)
BY MR. BONELLA:
Q If we go to this page and we go to the time of 5.0003 seconds --
A Yes.
Q -- the Z value is 115.199. Do you see that?
A Yes.
Q So the Z value from time equals 4.002, time equals 5.0003 for sample 1 actually went down.
A Yes.
Q Why is that?
A I don't remember. I'd have to look at the entire curve, but --
Q We'll just mark the page that we're looking at now as Exhibit 409, the page that has the 5.0003 seconds.
(DePuy Mitek Exhibit No. 409 was marked for identification.)
THE WITNESS: You're talking about one

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BY MR. BONELLA:
Q Let me show you Exhibit 410 and 411. I think Exhibit 410 is the coated results from the friction test, and Exhibit 411 is the uncoated results from the friction test, right?
A Yes.
Q Let's look at Exhibit 410 for a minute. The data show, for example, one, under that it says radius. Do you see that?
A Yes.
Q What is that?
A It's a relevant parameter for this test, which is always shown.
Q What is the radius?
A It makes sense for the rotary motion, but not for the linear motion.
Q What is it?
A It's a radius of rotary motion, which makes no relation to -- has no relevance to the linear motion.
Q You didn't have the rotary motion driver here, did you?
A Right, this is why it was not supposed to be recorded.
Q What's set force? What is that?

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A Set force was 2 newton, or 200 grams.
Q That's the force in the Z direction?
A Z force.
Q That's minus because it's pushing down?
A That's correct.
Q The next one is duration. What is that?
A It's just times 100 seconds.
Q The next one is --
A If you look at the data, it's 100 seconds.
Q Next one is entry something?
A We already discussed. It's number of data point, frequency of data acquisition.
Q First column is FX. What is that?
A Friction force.
Q Next column is FZ, what is that?
A Normal load.
Q So that's the one you were trying to keep constant?
A Yes.
Q Looks like it varied.
A Yes.
Q So it wasn't constant?
A If you measure normal load, it's never ever constant, so you try to maintain it as

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constant as possible.
Q What happens if it's not constant?
A Pardon me?
Q If it's not constant, that means the upper suture is actually moving relative -- it's actually moving relative to the lower suture in a vertical direction, correct?
A Right, correct.
Q T is time and seconds?
A Yes.
Q In the distance, if the upper suture moves relative to the lower suture, that affects the friction force, right?
A Yes.
Q Z is what?
A Z is still vertical displacement in millimeters. So the original displacement, it's like zero, and you can calculate practically the rear depth of the suture. You have to do this test longer, for several minutes. You can wear out the suture, and Z will give you the dynamics of the depths of wear.
Q So Z just actually shows the relative motion of the upper suture to the lower suture?
A Yes.

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Q F sub F, what is that?
A I'm sorry, like last time, I don't know.
Q F sub X and F sub F look like they're the same except -- the same magnitude, different in negative or positives. See that?
A I don't know.
Q You don't know?
A I have to consult my engineer. I don't remember what's is FF.
Q How about COF, what's that?
A That's a coefficient of friction, ratio of FX over FZ.
Q So FX divided by FC should give me COF?
A Yes.
Q Did you have to put any other parameters in the machine for the calculation of coefficient of friction, or is it just strictly that ratio?
A No, it's just ratio of friction force of a normal load.
Q See the average coefficient of friction data that you presented?
A Yes.
Q When you say average, did you take it across the whole time you did the sample, or did you just do it over a portion of the time?

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A No, over the entire hundred seconds.
Q Okay. Why does it change initially, drop off right away, like it's the only curve where it drops?
A There is always some so-called run-in period or burnishing period. When you put two surfaces together, there's always some change in friction in the beginning until they get adjusted to each other.
Q Do you have any idea whether -- see how you got the average for point -- coated was .09, uncoated was 0.16?
A Yes.
Q Do you have any idea of how big of a difference that is relative to other sutures?
MR. TAMBURO: Objection, vague.
THE WITNESS: Relative to others sutures?
BY MR. BONELLA:
Q Like do sutures typically test in values of .08, or do they typically test in values of .8 or 2? Do you have any idea what the typical results are for a suture?
A I don't remember right now, but I do remember that we compared data to several

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references, and data was of the same order of magnitude.
We compared to data of -- published data of several authors, and they had the same order of magnitude.
Q What do you mean they had the same order of magnitude?
A The friction is around .1.
Q Are you sure about that?
A Yes, I am.
Q Okay. And if it isn't?
A Huh?
Q If it isn't?
A Then somebody published wrong data.
Q Let's go back to this exhibit, 407 -- 410. 1.9, the first point, FX, and FZ is 199.386 of magnitude. If you divide them, my consultants here tell m you get 0.0095945.
A Right.
Q Which is not 0.139, which is the coefficient. If that math is correct, how do you explain why the coefficient of friction is different?
A I don't know, because as I said, I'm confused a little bit by this FF and FX. I have

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to clarify this with my engineer what is FX and what is FF.
Q They're the same, so you said coefficient of friction was FX divided by FZ.
A Yes.
Q If this math is right, that means coefficient of friction is not FX divided by FZ. It's not F divided by FZ either.
A I have to clarify.
Q So you don't know how coefficient of friction was obtained?
A I know very well the coefficient of friction was obtained as a ratio, but I have to clarify columns FX and FF.
Q So you don't know what it is a ratio of?
A It's supposed to be a ratio of friction force over normal load.
Q Isn't FX the friction force, or FF the friction force?
A This will be my assumption.
Q They're the same value, so it shouldn't matter which one you use?
MR. TAMBURO: Objection, asked and answered.
BY MR. BONELLA:

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Q Right?
A Right.
Q So sitting here today, you can't really tell me how you get coefficient of friction from this data?
A Right.
Q The next section is the chatter data. You said that the chatter data measured from both the knot run-down and suture-on-suture friction tests are summarized in Table 5 below.
Do you see that?
A Yes.
Q How did you determine the values that are in Table 5 from the two tests?
A If we talk amplitude of friction fluctuations from the knot run-down test and from amplitude of friction fluctuations from the suture-on-suture test, we just took the ratio as their average.
Q Let me back up. You say the variation in amplitude. Are you saying from each high point to each low point in each test you calculated it, or --
A No, no, no. We calculated not each and every point, but we calculated the average

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amplitude of fluctuations.
Q Average amplitude of fluctuations. I don't understand what you mean.
A It consists of each and every point, but for the sake of Table 5, we talk only average from Figure 11 and average from Figure 8.
Q Are you saying you took the average from Figure 11 --
A Average amplitude. Average amplitude from Figure 8, average amplitude from Figure 11, and we took their average as amplitude for Table 5.
Q So you got the average amplitude for Figure 8 -- wait.
A Yeah, it's true.
Q It's difference in amplitudes, right? Chatter isn't the difference in amplitude?
A No, chatter is amplitude. Chatter is amplitude of fluctuations. So if you look -- for example, let's look at uncoated in Figure 11.
Uncoated in Figure 11 has amplitude from about .15 to about .17. It's .02. So amplitude is .02. Are you with me?
Q Are you saying basically you just looked at the graph, you drew a line that was along the

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highest peaks here, and then looked at the line on the bottom and said the amplitude is .02?
A Yes.
Q How did you know where to draw the line? Like the beginning part goes down the curve. Did you omit that part?
A You don't really do it manually on the plot. You do it in the computer automatically, and --
Q Let me back up. Did the computer generate the values, or did you calculate them or get them from the graph for chatter?
A Amplitude of fluctuations is automatically produced by the computer.
Q By the computer, okay. Is that shown in the --
A Unfortunately not because secondary parameters. The recorded data in our software is only the original data, like force displacement, but what you calculate, statistical analysis, unfortunately, is not recorded.
Q Is it gone?
A Yeah.
Q You don't have it anymore?
A So this is what you have table for.

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Q Is there some computer program that's in the machine that generates the difference in the amplitude for the Figure 8 and Figure 11 curves?
A Yes.
Q Can you tell me the math that is used to do that?
A The math will calculate the amplitude --
Q I mean, does it figure the average high point and the average low point, and then take the difference between the two, or does it take each high point with the next low point and take those differences and average them, or how does it work?
MR. TAMBURO: Objection, vague.
THE WITNESS: Can you please repeat?
BY MR. BONELLA:
Q Sure. One thing you could do, I just don't understand how the computer is doing this. One thing you could do is you could take this high point to the next low point, high point to low point, and you figure out that difference for each time and average them; or you can figure out what the high point was, the average high point and the average low point, and take the difference between those two.
A Yes.

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Q Or there could be some other way you could do this. I don't know.
A Yeah, I do not remember. I'm sorry.
Q You don't know?
A No.
Q How about for determining it from the other figure, Figure 08, do you know how that was done?
A Same thing.
Q If you look at the Table 5 chatter data --
A Yes.
Q Do you know why sample 6 had a chatter data value of 0.012 for coated, which was greater than the uncoated suture chatter data value? Do you know why?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: Your question is whether -- I see it here. Yes, I see it.
BY MR. BONELLA:
Q Yeah. That's saying sample 6, coated, got a greater chatter value than sample 6, uncoated.
A Yes, I see it, yeah.

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Q Can you explain why?
A No, I cannot.
Q The next test is the tissue drag tests, right?
A Yes.
Q It says two types of tests were performed, dragging the suture through the hole made with a needle, and dragging the suture between two tightly clamped pieces of leather.
A Yes.
Q In both cases, the upper end of the suture was attached to the UMT upper bracket, providing the well controlled motorized dragging action. Do you see that?
A Yes.
Q Do you see the curves in Figure 13?
A Yes.
Q Are those for the tests for dragging the suture through the hole made with the needle? Are those for the tests of dragging the suture between two tightly clamped pieces of leather?
A These curves are result of needle.
Q Are what?
A In the case -- in the second case, without the needle.

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Q So Figure 13 is a tissue drag test without the needle test?
A Correct.
Q How about the Table 6 data?
A Same thing.
Q Where is the results of the tissue drag with the needle?
A We did not present them because average was the same.
Q So you did the tissue drag tests with the needle, you just didn't present the results?
A We started doing with the needle, then we switched to the clamp, we found no difference, and we continued with the clamp.
Q Yeah, okay. You did it with the needle, you didn't present the results. Do you still have the results?
A No, we do not.
Q What happened to them?
A We did not save them. I assume we overwrote the test file with the data from the clamp.
Q You overwrote -- you just said -- you just said you did the clamp first and the needle --

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A No, no, we started from the needle, then we decided to switch to just clamp and get rid of the needle, and we found results are the same, so we discarded needle and proceeded only with clamping the suture between two pieces of leather.
Q Do you have any results at all from the needle testing that we can look at to assess your statement that the results were the same?
A No, we do not have.
Q The test with the needle, let's do the -- I'm sorry, let's do the clamp test first. If I can call it the clamp test, is that okay, the tissue drag clamp test?
A Uh-huh.
Q So that was done by clamping a suture between two pieces of leather; is that right?
A Yes.
Q And how is the tension controlled on the clamp?
A I'm sorry, which tension?
Q The clamping the suture between two pieces of leather, right?
A Yeah.
Q And the clamp is a metal clamp with a nut and bolt, right?

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A Yes.
Q How are you controlling the tension or the forces that are applied by the clamp controlled by the nut and the bolt?
A We didn't control it.
Q You didn't control it, okay.
Now, so the suture is sandwiched, if you will, between two pieces of leather, right?
A That's correct.
Q And then the upper part of the suture is pulled; is that right?
A Pulled up, yeah.
Q And you used a 20 millimeter gauge length, right?
A Yes.
Q So is that the same for all samples?
A Is the same?
Q Was the 20 millimeter length the same for all samples for the clamp tissue drag?
A Yes.
Q And you did this test by pulling a constant rate. You did the tissue drag clamp test by pulling at a constant rate of 1 millimeter per second?
A Yes.

EXHIBIT 11

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-O-

DEPUY MITEK, INC., a Massachusetts Corporation,	:	Civil Action No.
Plaintiff,	:	04-12457 PBS
-vs-	:	
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	:	EXPERT DEPOSITION OF:
	:	ROBERT T. BURKS, M.D.
Defendants.	:	

-O-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

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A. I would say it was probably 45 minutes plus ten minutes.
Q. Did you tie knots in each of the individual five sutures from suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. Yes.
Q. After you performed the tactile feel analysis and knot tie-down, as reflected in Exhibit 232, what did you do with the sutures that you tested?
A. I pitched them with the spools.
Q. You threw them out?
A. Yes.
Q. Did counsel ever instruct you to not throw away the samples?
A. No.
Q. Did counsel give you any instructions at all what to do with the samples once you performed the tests on them?
A. No.
Q. Did you throw them away at home or at the office?
A. At home.
Q. And then once you completed the tactile feel analysis and knot tie-down analysis and once you

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threw away the sutures, what did you do next?
A. Well, as it regards this, I sent an e-mail to Sal and said here's what I thought.
Q. Do you have a copy of that e-mail?
A. Nope.
Q. What did you do with the e-mail that you sent to Sal after you concluded the tests?
A. What did I do with the e-mail? I didn't do anything with the e-mail. I hit "send".
Q. It's still on your computer?
A. I would doubt it's on the computer. I mean, just due to the volume, they don't keep three months or four months or whatever.
Q. Did you send it from work or home, the e-mail?
A. I don't know for sure.
Q. You don't know for sure?
A. No.
Q. Did you delete the e-mail you sent to Sal after you finished performing the tests?
A. I'm not sure I understand deleting the e-mail. I sent him an e-mail. I didn't purposefully delete any e-mail.
Q. Do you use Microsoft Outlook for your e-mails?

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A. No.
Q. What program do you use for your e-mails?
A. At home it's a Comcast e-mail and then here it's a Group-Wise.
Q. But do you use -- what e-mailing system do you use at home? Is it AOL or Lotus Notes or Microsoft Outlook or a Yahoo account?
A. It's a Comcast.
Q. That's done on a personal computer?
A. Yes.
Q. What about in the office? What kind of e-mailing system do you use?
A. We call it Group-Wise.
Q. Is the e-mail account you have at home different than the one you have at the office?
A. Uh-huh.
Q. Did you look for the e-mail in response to the subpoena, Exhibit Number 231?
A. Yes. The e-mail -- I mean, my awareness of the e-mails is that they go back two or three weeks or so and then after that they just go into cyberspace.
Q. So you did not look for the e-mail in response to the subpoena, Exhibit 231?
A. No, because that was like three months

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ago.
Q. When you say the e-mails go back two or three weeks and then go into cyberspace, you are referring to work e-mail or your home e-mail?
A. Well, primarily, I guess I'm referring to the work one. I don't use the home as much. So I don't. . .
Q. Do you remember what the e-mail said that you wrote to Sal after you performed the tests in Exhibit 232?
A. Pretty much what's in here. I just said, you know, sample A to me felt this way compared to sample B.
Q. Felt -- what word did you use to describe how suture A felt in relationship to suture B?
A. I don't remember specifically but, I mean, I probably used a word like "smoother".
Q. But you are not sure?
A. I'm not sure of the word.
Q. Did Sal send an e-mail back to you once you sent him the e-mail after completing the tests in Exhibit 232?
A. Not that I remember specifically.
Q. When was the next time you spoke to Sal after sending the e-mail on which you completed the

EXHIBIT 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

- - -

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff	:	CIVIL ACTION
vs.	:	
ARTHREX, INC., a Delaware Corporation and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom, Defendants	:	NO. 04-12457 PBS

- - -

Video Taped Deposition of

DR. NORM GITIS, was taken pursuant to notice at the Law Offices of Woodcock Washburn, 2929 Arch Street, Philadelphia, Pennsylvania, on Wednesday, July 18, 2007, beginning at 9:00 a.m., before Jeanne Christian, Court Reporter-Notary Public, and Robert Higham, Video Tape Operator, there being present.

- - -

APPEARANCES:

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Phone: (202) 420-5164
Representing the Defendants

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DR. NORM GITIS

EXHIBITS

THE VIDEO TAPE OPERATOR: We are on the record. This is a video tape deposition for the United States District Court for the District of Massachusetts. My name is Robert Higham. I am the video tape operator. I am employed by Veritext. The court reporter is Jeanne Christian.

The caption for today's case is as follows: DePuy Mitek versus Arthrex, Incorporated; Civil Action Number 04-12457.

This deposition is being taken on behalf of the Plaintiff at the law offices at 2929 Arch Street, Philadelphia, Pennsylvania.

At this time, I will ask counsel to identify themselves for the record.

MR. BONELLA: Michael Bonella, Dianna Elderkin and Eric Falke for the Plaintiff, DePuy Mitek.

MR. TAMBURO: Salvatore Tamburo for Defendants Arthrex, Inc. and Pearsalls Limited.

THE VIDEO TAPE OPERATOR:

The deponent today is Doctor Norm Gitis. Today's date is July 18, 2007. The camera time is 9:24.

The reporter will now swear in the witness.

DR. NORM GITIS, after having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. BONELLA:

Q. Good morning, Doctor Gitis.

A. Good morning.

Q. I show you DePuy Mitek Exhibit 581, subpoena to you.

Have you seen that before?

A. I saw -- I believe I saw only the first part of it, not the attachment.

Q. The attachment being the Complaint?

A. Yes, Amended Complaint, I didn't see.

Q. Did you see Page -- it is Page 2. It is Schedule A. It is the fourth page of the document, but it is labeled Page 2.

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A. Yes.
Q. Where it lists -- the next page after that. There you are.
Do you see where it says document requests and it has a list?
A. Yes, sir.
Q. Did you review those?
A. Yes, I did.
Q. What did you do to search for documents that were requested?
MR. TAMBURO: Excuse me. I'm just going to object to the extent that Defendants have already notified Plaintiffs, Plaintiff that there are objections to certain of these requests, and I will just -- for example, you know, some of them are overbroad, they go to subject matter covered by the first deposition of Doctor Gitis, and some of them go to subject matter that is outside of the scope of the deposition, according to the Court's order.
So I'm not going to go into detail about which is -- which request is outside the scope, I don't want to take that time now, but I'm just going to say for the

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record that some of these are overbroad and improper and outside the scope of the Court's order.
MR. BONELLA: Are you withholding any documents based on relevance or breadth of the request?
MR. TAMBURO: Are you asking me?
MR. BONELLA: Yes.
MR. TAMBURO: There is one document that I think is outside of the scope.
MR. BONELLA: That you are withholding?
MR. TAMBURO: Yes.
MR. BONELLA: What is it?
MR. TAMBURO: A document that goes directly to the virus.
MR. BONELLA: It goes directly to the virus, and you are withholding it?
MR. TAMBURO: Yes.
MR. BONELLA: Who is it authored by?
MR. TAMBURO: Not the witness.

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MR. BONELLA: Counsel?
MR. TAMBURO: Yes.
BY MR. BONELLA:
Q. Back to my question, Doctor -- obviously, we disagree, and we will resolve it later.
Doctor Gitis, what did you do to look for documents that were requested in the subpoena, Exhibit 581?
A. First of all, I want to say that I saw the subpoena only yesterday, so what I did, I printed out all the e-mail communications between our company and the legal office that Sal Tamburo is representing, and also I printed out all the invoices submitted by our company to the legal office in Arthrex.
Q. And you gave all those documents to counsel?
A. Yes.
Q. Were there any -- did you have any documents related to your investigation surrounding your expert report that detailed your work or analysis regarding your investigation, other than the e-mails and the invoices?

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MR. TAMBURO: Objection. Which expert report?
MR. BONELLA: Any expert report.
THE WITNESS: We also had the reports themselves.
BY MR. BONELLA:
Q. Besides reports themselves, but any documentation, work you did, either while you were doing your investigation, notes, or work you did to figure out what -- about a virus or the effects of a virus or any documents, notes you made or the gentlemen that work with you made?
A. Also, one more thing we have raw data from our tests, one CD we submitted to you last year, and another CD we submitted to the counsel recently.
Q. In addition to those that you have already identified, are there any notes or work or details of the work that you -- surrounding your investigation regarding your expert report and the work that you and the gentlemen you work with did to try to investigate any issues with your expert

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report? Did you guys keep any work and any documents that document any work you did?
A. No, there are no more documents.
Q. Have you had any communications with Doctor Muckergie since the last time you were deposed?
A. I don't remember having any communications with him afterwards.
Q. Have you had any communications with anyone from Arthrex since the last time you were deposed?
A. No, I don't remember having any communications with Arthrex.
Q. Have you had any communications with anyone from Pearsalls since the last time you were deposed?
A. I have never had any communications with Pearsalls.
Q. Have you had any communications with a Doctor Burks since the last time you were deposed?
A. No, I haven't.
Q. Have you had -- other than counsel, have you had any communications with anyone connected with this litigation since the last

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time you were deposed?
A. In addition to counsel, I also had communication -- had one or two phone calls with another lawyer, Jack --
Q. Mr. Zaber?
A. Yes, yes.
Q. Other than Mr. Tamburo and Mr. Zaber and people who you work with, have you had any communications with anyone connected with this litigation since the last time you were deposed?
A. No, I haven't.
Q. How about the gentleman who took the photomicrographs that are in your expert report? Have you had any communications with him since the last time you were deposed?
A. Sorry, what micrographs?
Q. The pictures of the sutures in your expert report? Do you remember those?
A. You mean SEM photographs or our photographs?
Q. The photographs, right, in your expert report?
A. No, no communications.
Q. So you have had no communications with

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the people who took the photographs that are in your expert report?
A. No.
Q. Let me just clean that up.
You have had no communications with the people who took the photographs in your expert report since your last deposition?
A. I'm sorry. Are you talking about photographs or SEM photos? The kind you get with microscope or just photos of the sutures?
Q. Let me show you your expert report, Exhibit 381.
MR. TAMBURO: I'm just going to object to the extent this questioning goes to something other than supplementation of this report per the Court's order.
BY MR. BONELLA:
Q. If you turn to Page 14 and 15?
A. Yes, SEM photos.
Q. Right.
Have you had any communications with the folks who took those SEM photos since your last deposition?

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A. I believe that we requested them to do another SEM photo for completely different case, completely unrelated to this, and we have not had with them any communications on this case.
Q. What is a typographical error, in your mind?
MR. TAMBURO: Objection, vague.
THE WITNESS: What is a typographical error?
MR. TAMBURO: Objection to the extent the witness is being asked to interpret the Court's order.
THE WITNESS: What is a typographical error? In general, we have to look at the dictionary.com, but I believe that typographical error is when a letter or a number or several letters or numbers are typed wrongly.
BY MR. BONELLA:
Q. So as a general statement, would you say a typographical error is when you intend to type one thing, but you type something else instead?

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MR. TAMBURO: Objection, vague.
THE WITNESS: I believe it is a good definition.
BY MR. BONELLA:
Q. How about a calculation error? What would you consider a calculation error to be?
A. Calculation error when result of calculations does not correspond to the correct commonly accepted calculation methods.
Q. Kind of like a math error, an addition, subtraction error, something like that would be an example of a calculation error?
A. Yes.
Q. I show you DePuy Mitek Exhibit 582. I ask you if you recognize that.
A. Yes, that's my October supplemental report.
MR. TAMBURO: I'm going to object to the extent this report is not part of the scope of this deposition, and depending on the questions, we may have a big problem today.
MR. BONELLA: Are you representing that Arthrex is in no way relying

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on the report, the October report, Exhibit 582?
MR. TAMBURO: Are you asking me?
MR. BONELLA: Yes.
MR. TAMBURO: Yes, we have previously said that.
BY MR. BONELLA:
Q. Let me show you DePuy Mitek Exhibit 583. I ask you if you recognize that.
A. Yes, I do.
Q. And what is Exhibit 583?
A. It is my supplemental test report, dated June 28, 2007.
Q. Does Exhibit 583 contain all the supplements you intend to testify about at trial to your original report?
A. To the best of my knowledge, yes.
Q. Is there anything in your deposition that you didn't know about when I asked you or you were confused about the time or any other mistakes in your original expert report that you intend to talk about that aren't discussed in Exhibit 583?
A. I am sorry. Very complicated question.

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Q. Sure.
I just want to know if there is anything else you want to change about your deposition or your original expert report, your testimony at your deposition or your expert report, your original one?
A. I'm not changing things. I'm not changing anything, and I don't want to change anything.
Q. You are saying you didn't make any changes to your original expert report?
MR. TAMBURO: Objection, mischaracterizes his testimony.
THE WITNESS: I -- if you are asking about supplemental test report, it provides more explanations to our last year original report, but if you are asking whether we have any additional supplements, at this point, we don't have any additional considerations, and we are not planning to file any new supplements.
Q. Is there anything you didn't know at your deposition that you want to -- that you have gone back and looked at, and now, you know the answer to those questions?

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MR. TAMBURO: Objection, vague.
THE WITNESS: I'm sorry.
BY MR. BONELLA:
Q. Do you recall your deposition, I asked you some questions, a lot of questions, and sometimes, you didn't know the answer about the data with the various tests? And my question to you is, is there any -- have you gone back and looked, and do you know the answer to those questions now?
A. It is possible, yes.
Q. It is possible, but they are not -- not anything that is not in your expert report, Exhibit 583, your supplemental report, is there anything you intend to testify about that you didn't put in there?
A. My supplemental test report answers some of the type of the errors found in the original report, but it does not -- as far as I understand, the goal of the supplemental test report was not to answer all the hundreds of questions that I was asked during the previous deposition.
Q. Did you investigate any of those answers

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to -- are there any other questions that I asked where you didn't know the answer at the deposition? Did you investigate those and intend to testify about them at trial?
A. I think so.
Q. You did? And what other questions do you remember investigating?
A. I don't remember at this point of time, but whatever is related to the original test report and to the supplemental test report, I am ready, and I have to testify.
Q. So you have additional information that you didn't know at the deposition that's not in your expert -- supplemental expert report? Is that what you are telling me?
A. Can you please repeat?
Q. Sure.
So there were questions that I asked you at your deposition that you didn't know the answer to, right? Regarding the data and the tests, right?
A. Yes.
Q. And now, you have submitted a supplemental report, Exhibit 583?
A. Yes.

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Q. Are there -- is there information that you investigated and found out since the deposition that you have not included in Exhibit 583 that you intend to testify about?
MR. TAMBURO: Objection, vague.
THE WITNESS: If there are no changes to the original -- if I am under the impressions that I don't have to change the original test report, I believe I don't have to supplement it. So the supplemental test report to my understanding is dealing with substantial modifications, changes, explanations to the original report, but as I -- again, I just can repeat that I did not try to answer all the questions asked me during the deposition in the supplemental report.
BY MR. BONELLA:
Q. So you do have additional information regarding the questions I asked at the deposition where you didn't know the answer that you have not included in the supplemental expert report?
A. Yes.

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Q. Do you know what those items are that you intend to testify about that you haven't included in the supplemental report?
A. No, as I said, I cannot think about this right now.
Q. If you go to your supplemental report under the section pliability test, do you see that?
A. Yes.
Q. Exhibit 583, Paragraph 2.1 states: Our March 2006 report erroneously stated that the tests were performed at the continuously increasing load stress at the rate of 0.33 KG/S.
Do you see that?
A. Yes.
Q. So if you go to Exhibit 381, the original report?
A. Yes.
Q. On Page 3?
A. Yes.
Q. And that original report, you stated that the same pliability tests were done with a uniformly -- I'm sorry -- were performed with a pre-load suture was pulled at a force

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uniformly increasing at the rate of 0.33 kilograms per second, right?
A. Yes.
Q. So that was incorrect in your original report?
A. Yes.
Q. Was that a typographical error?
A. No.
Q. Was it a calculation error?
A. No.
Q. Why in your original report did you think the pliability test was performed by uniformly increasing the load at a rate of 0.33 kilograms per second?
A. It was some miscommunication between me and the test engineer who conducted the test. I was under the impression that he will do the test at the -- with the continuously increasingly force load, and I did not -- and I did not realize until the deposition, when you pointed it to my attention, that he did the test differently.
Q. So you instructed your technician to perform the pliability test with a uniformly increasing load at a rate of 0.33 kilograms

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per second; is that correct?
A. I instructed him to increase the load the way we did it in order for our large customers like United States Surgical or Ethicon, and we did it, I thought, at the .33 kilogram per second rate, but somehow, he decided that the better, the cleaner way, the better way, the more correct way to conduct this test is to increase the extension deformation, and somehow, it got lost in communications. He said that he told me clearly, and I never remembered him telling me this.
Q. So you instructed your technician to perform the pliability test at a uniformly increasing load rate of 0.33 kilograms per second; correct?
A. Yes.
Q. And your technician did not perform the pliability test in accordance with your instruction; correct?
A. Yes. He tried to do it better.
Q. Did he communicate that to you before he did the test?
A. He believes he did.

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Q. So with respect to the pliability test at least, there was miscommunication between you and your technician, and the technician performed the test differently than you intended it to be performed, right?
A. Correct.
Q. Do your technicians have latitude to change the parameters of the tests?
A. Yes.
Q. Did your technicians review your expert reports?
A. I believe he did, and he believes that he just looked at the results, and he didn't pay attention to the details.
Q. So your technician looked at the result -- at the expert report before you signed it?
A. Yes.
Q. And they reviewed the results, but not the description of the test?
A. Yes. He kind of -- he missed it. He missed it, and I missed what he believes that he told me that he did it at the increasing rate of extension, and he missed that I actually wrote increasing rate of load.
Q. So he didn't tell you that the

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description of the test was wrong when he read the report?
A. He did not tell me until after the deposition, when I came back to the office and started discussing with him how to -- how exactly the test was conducted.
Q. Did you discuss with your technician -- let me back up.
Were you really present when this test, pliability test was performed?
MR. TAMBURO: Objection, objection, argumentative.
THE WITNESS: Yes, of course.
BY MR. BONELLA:
Q. You were?
A. Yes.
Q. And you didn't know which way he was doing the test, constant increasing force or constant extension?
A. Looks like I didn't pay enough attention.
Q. So, now, in your new expert report, supplemental expert report, Exhibit 583, you

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say the constant extension rate -- the average constant extension rate for all samples was 0.113 millimeters per second, right?
A. Yes.
Q. And then you calculated new pliability data for each of the samples on Page 2 based on using that assumption or analysis that he had a constant extension rate?
MR. TAMBURO: Objection, mischaracterizes the document.
THE WITNESS: I am sorry. What is your question?
BY MR. BONELLA:
Q. Sure.
Paragraph 2, you are saying that the test was performed at a constant extension rate?
A. Paragraph 2.1?
Q. Right, yes. And then, based on -- let me go ahead to Paragraph 2.2.
In Paragraph 2.2, you state that your March report had a typo, stating the suture diameter was 0.65 millimeters, instead of an intended 0.56 millimeters?
A. Yes.

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Q. Do you believe that 0.56 millimeters was a typographical error?
A. Likely.
Q. Likely? Do you have memory of measuring of 0.56 millimeter diameter?
A. At this point, at this second, I don't have exact memory of what we measured, but most likely, it was .56, and there was a typo, and we wrote .65.
Q. Do you recall whether or not when you typed the original expert report whether you intended to type 0.65 or you intended to type 0.56?
A. I cannot guarantee for sure. I believe I meant -- I intended to type 0.56, but I don't have a document to prove it.
Q. I'm not asking what you believe. I'm asking what you remember. Either you remember it or you don't remember it.
Do you remember, when you typed the report, whether you intended to type the 0.56 or 0.65?
A. I don't remember for sure at this point of time.
Q. And you have no documents that would

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indicate one way or the other?
A. I already said in my original deposition that we didn't keep documents of this measurement.
Q. So in your first report, you are saying now -- your testimony now is that when your first report said 0.65 millimeters in diameter, that was incorrect?
A. Most likely, it was a typo, and most likely, the correct number was 0.56.
Q. Most likely? Which -- so you really don't know which it was?
A. I do not know for sure.
Q. On Page 2 of your supplemental report, Exhibit 583, you have a pliability test data chart.
Do you see that?
A. Yes.
Q. You calculated that new chart?
A. It is not a chart. It is a table.
Q. Okay, table.
You calculated the pliability test table based on the 0.65 millimeter diameter?
A. No, no, based on 0.56 millimeter

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diameter.
Q. I'm sorry, I misspoke.
A. The original report of March of last year assumed 0.65 millimeter. And this supplemental report has Table 1A, which recalculates the original Table 1 with a diameter of 0.56.
Q. And then the knot slippage strength test in Paragraph 3.1 -- I'm sorry. Before I get to that, did you do any statistical analysis on the data that you have in Table 1A?
A. I did statistical analysis on the original data that I have in Table 1 of the last year report. I didn't repeat it for Table 1A, which is supplemental report.
Q. And the statistical analysis would not be the same because the data is different, right?
A. Correct.
Q. So you did not do a statistical analysis for the data in Table 1A of Exhibit 583?
A. That is correct.
Q. Your knot slippage strength test, you discuss in Paragraph 3.1 of your supplemental report?

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A. Yes.
Q. Now, you say your March 2006 report was erroneous in that it stated the test was performed at a constant speed of one millimeter per second; is that correct?
A. Yes.
Q. And now, you say that the analysis of data shows that the test was performed at 0 point -- at roughly 0.134 millimeters per second, right?
A. Yes.
Q. And if you go to your original report, Exhibit 381, and you go to the description of the knot slippage strength test on Page 5 of your original report?
A. Yes.
Q. It says: The parallel rods were then pulled apart at a constant velocity of one millimeter per second in the middle of the paragraph.
Do you see that?
A. Yes.
Q. So that was a mistake in your original report?
A. Yes.

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Q. Did you intend to type that when you typed it?
A. It was not a typo. It was a mistake.
Q. It was not a typo?
A. Not a typo.
Q. And it was not a calculation error?
A. No.
Q. Any other -- so in Exhibit 583, you identify at least three mistakes in your original report, the way at which the pliability test was conducted, the diameter measurement and the speed at which the knot slippage strength test was conducted, right?
A. I don't believe that it was at least three mistakes. There were just precisely three mistakes.
Q. Well, the pliability test data was then different, right?
A. Yes.
Q. So that would be another difference, right?
A. Yes.
Q. Okay.
Other than those, any other mistakes in your original expert report?

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A. I don't think so.
Q. Now, you did not supplement to discuss the knot run-down tests in your original report? You didn't have any supplementation regarding those?
A. Correct.
Q. Do you still intend to rely on the knot run-down test at trial and talk about those?
A. Correct.
Q. The friction tests in your original report, do you intend to rely on your original friction test that you did at trial and talk about those?
A. It depends on the counselor. I don't know where -- I agree to -- I am ready to testify and to rely on all the tests in the original report with the consideration of the supplemental report.
Q. So you think the analysis and the results of the friction test that you presented in your original report, Exhibit 381, are satisfactory to present to the jury?
A. Yes.
Q. And you think they are good results and good to rely on, the friction test results in

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your original report?
A. Yes.
Q. How about the chatter data in your original report? Do you intend to rely on the chatter data and results and tests that you did at trial?
A. Yes.
Q. How about the tissue drag tests that are in your original report? Do you intend to rely on those at trial?
A. Yes.
Q. I would like to go back to your first report, Exhibit 381, your original report?
A. Yes.
Q. If you turn to Page 17, please?
A. Yes.
Q. Is that your signature on Page 17?
A. Yes.
Q. What does your signature mean when you sign a document such as an expert report?
MR. TAMBURO: Objection. This is just -- I'm sure you asked him this same question. How is this related to the supplement?
MR. BONELLA: It is related

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to the supplement.
MR. TAMBURO: How is it related to the supplement?
MR. BONELLA: I'm not arguing with my deposition time. If you want to object, object.
MR. TAMBURO: I'm surely objecting. This is related to the first deposition, and you had seven hours plus a year ago to ask him these questions.
You can answer, if you know.
THE WITNESS: My signature means that I read and agreed with the content of this document.
BY MR. BONELLA:
Q. So when you signed Exhibit 381, you thought it was truthful and accurate?
A. Sorry?
Q. So you when you signed Exhibit 381, you thought it was truthful and accurate?
A. Yes.
Q. And it turns out it wasn't, right?
A. What is your definition of truthful?
Q. Well, it had mistakes.

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THE WITNESS: So I -- first of all, it is not that I believed that there was a virus. It is a fact that there was a virus. It is a fact that we had a virus. It is not a belief, but I do not know and I didn't know at that time whether it infiltrated lap computers or what computers have been infiltrated inside the company, I do not know.
BY MR. BONELLA:
Q. What was the name of the virus?
MR. TAMBURO: Objection. Do not answer, beyond the scope. I instruct him not to answer.
BY MR. BONELLA:
Q. When did the virus occur?
MR. TAMBURO: Objection. Objection, vague, asked and answered.
THE WITNESS: I do not remember for sure, since we opened our office in China, we have had several viruses coming into the system from Chinese communications, and when Chinese -- and I am not sure which virus was in suspicion to penetrate these test results.

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BY MR. BONELLA:
Q. Tell me all the viruses you had, names of all the viruses you had before April 2006.
MR. TAMBURO: Objection. Objection, do not answer. Beyond the scope of this deposition. It is a waste of your time and beyond the Court's order.
BY MR. BONELLA:
Q. Can you describe generally how the virus worked?
MR. TAMBURO: Objection. Same objection. Instruct him not to answer, since it is beyond the scope of the Court's order.
THE WITNESS: I am not an expert in viruses.
BY MR. BONELLA:
Q. Isn't it true that there was no virus that affected your data or your report?
MR. TAMBURO: Objection, argumentative and beyond the scope of this deposition. And I'm instructing you not to answer.
BY MR. BONELLA:
Q. Sitting here today, do you believe you

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had a virus that infiltrated the data in the report or not?
MR. TAMBURO: Same objection. Instructing you not to answer, beyond the scope of the Court's order and the deposition.
(Whereupon documents were marked as Exhibit 586 and 587 for identification.)
BY MR. BONELLA:
Q. I show you DePuy Mitek Exhibit 586. Do you recognize it?
A. Are you asking me?
Q. Yes. Have you ever seen it before?
A. I have never seen it. I am not among the receipts of this e-mail.
Q. This is an e-mail where your counsel told us that you thought you had a software virus, and it is dated July 24, 2006. Do you see that?
A. Yes.
Q. So as of July 14, 2006, you represented to counsel that you thought you had a software virus that would cause you to redo all your tests?

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MR. TAMBURO: Objection to the date.
MR. BONELLA: July 24, 2006, right?
MR. TAMBURO: I think you said 14th.
BY MR. BONELLA:
Q. As of July 14, 2006, you thought you had a software virus that would cause you to want to redo all your tests; right?
A. That's correct.
Q. And you have no documentation or anything regarding that virus?
MR. TAMBURO: Objection, beyond the scope, instructing you not to answer. I am instructing you not to answer.
BY MR. BONELLA:
Q. Have you concluded now that the virus -- that no virus affected any of your results or data?
A. No, I have not.
Q. You have not concluded that?
A. No.
Q. Are you certain that any test or data was not infected by the virus?

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remember.
BY MR. BONELLA:
Q. Let me rephrase it this way.
A. At least first time in writing.
Q. So some time between August 9th and August 28, 2006, is that when you thought there might be a typographical error?
MR. TAMBURO: Objection, mischaracterize testimony, assumes facts, vague.
THE WITNESS: Again, I am sorry, but I did not see the August 9 document. I spent three weeks in Europe in August because of some family circumstances, so I was completely unaware of August 9 report, and my declaration of August 28th in my mind was not reactive to the August 9 motion of DePuy.
BY MR. BONELLA:
Q. So at least this was the first time in writing, though, that you said there might be a diameter -- that's what you said, right?
MR. TAMBURO: Objection. Again, mischaracterizes testimony.
BY MR. BONELLA:

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Q. I will rephrase the question.
THE WITNESS: Some time after -- some time between June and August, 2006, I said to the counselors that it looks like we made a typo in the diameter in the original report.
BY MR. BONELLA:
Q. Why did you say there appears, as opposed to there is a typographical error in your declaration? Why did you say appears? Appears is fuzzy. It may be or it may not. Why did you say appears as opposed to is?
A. Because I don't like to speculate.
Q. You didn't say is, because you didn't want to speculate that, in fact, there was a typo?
A. I was not hundred percent sure that -- because I didn't have any document or proof whether it was .56 or .65, but you showed me the table which says that standard has to be between .55 and .59 or whatever, so I saw that probably, probably, it was a typo, but I was not -- I was not hundred percent sure.
Q. The other option is that you guys just measured it wrong, right? That's possible,

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too, right?
A. It is possible, but unlikely.
Q. Paragraph 9 of your declaration -- I'm sorry, let's go to Paragraph 13.
You said you found inconsistencies with the friction testing data collected. The calculations for friction co-efficient appeared to be correct for samples and incorrect for others. My initial belief was the only reasonable explanation for the intermittent miscalculations was a computer malfunction possibly caused by a virus as described below, as is still my belief.
What inconsistencies did you find?
MR. TAMBURO: Objection, beyond the scope, instructing you not to answer.
MR. BONELLA: Instructing him not to answer the inconsistencies found in the friction data?
MR. TAMBURO: Yes. It is not part of his supplemental test and beyond the scope of the deposition according to the

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Court's order.
BY MR. BONELLA:
Q. Do you plan on testifying about any inconsistencies, if you are asked at trial, in the friction data? Do you plan on explaining them?
MR. TAMBURO: Objection. When you say asked, do you mean on direct or cross?
MR. BONELLA: Either.
MR. TAMBURO: He can't anticipate what is going to be asked of him.
BY MR. BONELLA:
Q. If you are asked about the inconsistencies in your friction data at trial, do you plan on explaining what the inconsistencies were and how you found them?
MR. TAMBURO: Objection. Those questions are going to be beyond the scope during trial, too.
MR. BONELLA: Are you saying you are not relying on friction tests?
MR. TAMBURO: We are saying those questions -- I'm not saying that. I'm saying those questions you just asked are

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beyond the scope.
MR. BONELLA: How are they beyond the scope? How can they he beyond the scope?
MR. TAMBURO: Friction test is in his first report, and it is not in his supplemental report. This deposition is regard to the supplemental report.
MR. BONELLA: So you are instructing him not to answer questions regarding inconsistencies he found in the friction test data; is that right? I will move on, if you are.
MR. TAMBURO: Yes.
MR. BONELLA: So I can't ask any of those questions?
MR. TAMBURO: You have already asked several.
MR. BONELLA: I know, but I want to probe it, and I want to find out what the exact inconsistencies were, what the problems were, and you are instructing him not to answer?
MR. TAMBURO: That's correct, because of the Court's order.

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BY MR. BONELLA:
Q. Do you see Paragraph 14?
A. Yes.
Q. Talking about the loading rate?
A. Yes.
Q. And the pliability test rate?
A. Yes.
Q. You say: Based upon my subsequent investigation, I have since learned that this issue had nothing to do with data corruption.
Do you see that sentence?
A. Yes.
Q. So at one time, did you believe that any issues with the pliability test were due to data corruption, and then you later learned that it wasn't data corruption, it was interpreting the data or how the test was run?
A. Not necessarily. Originally, I was very concerned with the data corruption and friction test, and I suggested that counsel just redo all the tests independently on whether they were good or not, just to have a clean set of tests. Then when I was told that I have to analyze the data as is, and I have to do more analysis of the data inputted in my

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original report, instead of redoing the tests, then I did the analysis, and this declaration was the result of it.
Q. Did you ever provide specifics regarding the virus that you believe may have infected your system to counsel?
MR. TAMBURO: Objection, beyond the scope, instructing the witness not to answer.
MR. BONELLA: Let's take a break.
THE VIDEO TAPE OPERATOR: Off the record. The time is 10:36.
(Whereupon a short break was taken at this time.)
THE VIDEO TAPE OPERATOR: Back on the record. The time is 10:47.
BY MR. BONELLA:
Q. Doctor Gitis, I show you an exhibit we marked at your last deposition. It is Exhibit 402. I think we agreed at your last deposition, at least for your last report, that was the method you used to calculate the stiffness that was in your first report?
A. Yes, sir.

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Q. Is that correct?
A. Yes.
Q. So did you use this same method to calculate the pliability test data in your supplemental report, Exhibit 583?
A. Yes.
Q. Did you -- so the stiffness, as you calculated it, was basically a function of two parameters, the slope and the diameter of the suture, right?
A. Correct.
Q. Did you use the same slopes of the graphs that you used in your first test -- sorry, let me rephrase the question.
Are the slopes that you used to generate the pliability data in your first report the same as the slopes that you used to generate the pliability data in the second report?
A. Yes.
Q. Do you have any written documentation as to what those slopes were?
A. No. I have only you -- I'm sorry. In April or May of last year, we presented all the plots. Originally in March, we presented

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for all eight specimens. In the knot slippage strength test, I just compared first and eighth.
Q. And your plot showed the length going down over time?
A. Yes.
Q. Knot slippage strength, you were measuring that when it slides, you are measuring the friction between the sutures on itself as it slides before it failed?
MR. TAMBURO: Objection, vague.
THE WITNESS: Yes. Friction in the vertical direction.
BY MR. BONELLA:
Q. Surface friction of the suture?
A. Yes.
MR. BONELLA: Sal, he, at his last deposition, did not know what certain data was in the columns represented in his knot run-down test, his friction test. He didn't know how the chatter tests were calculated, T was calculated, and he didn't know some things with the tissue drag test. Are you going to object to

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him answering those questions? Are you going to instruct him not answer?
MR. TAMBURO: First off, I disagree with your characterization.
MR. BONELLA: I can give you an example.
MR. TAMBURO: Well, we are going to disagree, believe me, no matter what your example is, but I don't know -- all I know is, the Court said what this deposition is about. That's all I know. And we are complying with that. And if you ask him questions outside the scope, I'm going to object.
MR. BONELLA: Well, I want to get your opinion on whether it is or not, because --
MR. TAMBURO: Yes, everything you just mentioned is outside the scope, and I will instruct him not answer, correct.
MR. BONELLA: So, for example, in the -- I will give you an example.
MR. TAMBURO: Again, it depends on the question, but generally, yeah,

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it is outside the scope.
MR. BONELLA: So on the friction test, I asked him what the F sub F column was, and his answer was: I'm sorry, like last time, I don't know.
So I would like to ask him what that column represents. Are you instructing him not to answer that type of question?
MR. TAMBURO: I am following the Court's order. It is outside the scope.
MR. BONELLA: Are you going to instruct him not to answer that type of question?
MR. TAMBURO: Yes.
MR. BONELLA: So the chatter data, for example, the chatter data, he didn't know how it was calculated. Are you going to instruct him not to answer that?
MR. TAMBURO: Defendants disagree with your characterization of his testimony, and we will instruct him not to answer, because it is outside the scope of the Court's order for this deposition, yes.

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Again, depending on the question. If you ask him generally, yes, we are going to instruct him not to answer, but if you have specific questions that are not objectionable --
BY MR. BONELLA:
Q. How did the computer generate the chatter values in your first report?
MR. TAMBURO: Objection, outside the scope, instruction not to answer.
MR. BONELLA: Are you instructing him not answer?
MR. TAMBURO: Yes.
MR. BONELLA: Let's take a break.
THE VIDEO TAPE OPERATOR: Off the record. The time is 12:11.
(Whereupon a short break was taken at this time.)
THE VIDEO TAPE OPERATOR: Back on the record. The time is 12:17.
(Whereupon documents were marked as Exhibits 598 to 603 for identification.)
BY MR. BONELLA:
Q. Doctor Gitis, I would like to show you

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MR. TAMBURO: Objection. The response to that may call for information that's outside the scope of this deposition, and for that reason, I am instructing him not to answer to the extent it calls for information that does not go to a supplement. You can answer.
THE WITNESS: So I am --
MR. BONELLA: Are you instructing him not to answer or are you saying he can answer? You gave him both instructions.
MR. TAMBURO: I'm sorry. Let me make myself a little more clear.
The answer would require -- may require information that is outside the scope of the Court's order for this deposition.
MR. BONELLA: He doesn't know what that is.
MR. TAMBURO: Therefore, to the extent it does require disclosure of information that's outside the scope of this deposition, I instruct you not to answer. To the extent it is within, go ahead and answer.

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MR. BONELLA: How does he know what that is?
MR. TAMBURO: He read the order before we got here today.
BY MR. BONELLA:
Q. Do you understand the Court's order?
A. I understand it -- I believe I understand it. I am not an expert in understanding Court orders, but I was told to be prepared today to discuss my supplemental report. And I am not prepared at all to discuss the original report, which you already had the pleasure -- which I already had the pleasure to discuss with you last year.
Q. I just want to know if there is anything you want to -- anything additional that you didn't put in your supplemental report that you want to change about the original report or anything at your deposition last year that you want to change or add to your testimony, things you didn't know, is there anything that you know today that you want to add that you didn't know then or anything you want to change from your report or your testimony or your prior deposition?

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MR. TAMBURO: Same objection.
THE WITNESS: I just want to go home, so I don't have anything additional. I am not volunteering to offer any changes to my own reports.
BY MR. BONELLA:
Q. How about your deposition of last year? Is there anything additional you want to comment on, things you didn't know then that you know now that aren't in your supplemental report?
MR. TAMBURO: Same objection. To the extent it is beyond the scope of the deposition, I instruct you not to answer.
THE WITNESS: I am not sorry, I am not prepared, not prepared to add, to modify anything to the deposition.
MR. BONELLA: Subject to our disagreement about the scope of the deposition, we will obviously discuss that going forward and take it up by motion, if necessary, I think we are done.
MR. TAMBURO: Okay, no

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questions.
THE VIDEO TAPE OPERATOR: Going off the record. The camera time is 12:30. That completes this video tape deposition.

EXHIBIT 13

AO 88 (11/91) Subpoena in a Civil Case

United States District Court

FOR THE NORTHERN DISTRICT OF CALIFORNIA

DePuy Mitek, Inc.,
a Massachusetts Corporation

Plaintiff,

V.

Arthrex, Inc.,
a Delaware Corporation and

Pearsalls Ltd.,
A Private Limited Company
of the United Kingdom,

Defendants.

SUBPOENA IN A CIVIL CASE in the United States District Court for the District of Massachusetts

Case Number: 04cv12457 PBS

TO: **Norman Gitis**
1715 Dell Avenue
Campbell, CA 95008 USA

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. The deposition will be recorded by stenographic means and recorded by video and audio tape, and by instant visual display of the stenographic record.

PLACE OF DEPOSITION	DATE AND TIME
Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street NW Washington, D.C. 20037-1526 USA	June 21, 2006 at 8:00 a.m.

☒ YOU ARE COMMANDED to produce and permit inspection and copying of the documents and things set forth in Schedule A attached hereto at the place, dates, and time specified below:

PLACE	DATE AND TIME
Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street NW Washington, D.C. 20037-1526 USA	June 13 and 21, 2006 at 8:00 a.m.

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (ATTORNEY FOR PLAINTIFF)	DATE
Lynn Malinoski	6/8/06

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Lynn Malinoski, Woodcock Washburn LLP, One Liberty Place, 46th Floor, Philadelphia, Pennsylvania 19103, 215-568-3100

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO 88 (11/91) Subpoena in a Civil Case

PROOF OF SERVICE

	DATE	PLACE
SERVED		
SERVED ON (PRINT NAME)		MANNER OF SERVICE
SERVED BY (PRINT NAME)		TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
Signature of Server

_____
Address of Server

_____

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

© PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for depositions, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy the material or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
(I) fails to allow reasonable time for compliance;
(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(b)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
(iv) subjects a person to undue burden.
(B) If a subpoena
(I) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

Schedule A

Pursuant to Rule 45 of the Federal Rules of Civil Procedure and the Local Rules of the District of Massachusetts, Plaintiff DePuy Mitek, by and through its counsel, will take the deposition upon oral examination of Norman Gitis beginning on June 21, 2006 at 8:00 a.m. at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street NW, Washington, D.C. 20037 USA. The deposition will be conducted before an officer authorized by law to administer oaths and will be recorded by stenographic and video means. The deposition will proceed from day to day, weekends and federal holidays excluded, until completed.

Instructions and Definitions

1. DePuy Mitek has sued Arthrex in the United States District Court for the District of Massachusetts for Arthrex's infringement of U.S. Patent No. 5,314,446. A copy of DePuy Mitek's Amended Complaint is attached as Exhibit 1.

2. "Arthrex" means Arthrex, Inc. and includes each of its predecessors, successors, subsidiaries, divisions, and departments.

3. "FiberWire" means each Arthrex suture that is or have been sold under the tradenames FiberWire or TigerWire.

4. "Concerning" means referring to, relating to, commenting upon, evidencing or embodying.

5. "Communication(s)" means any transmission of information by one or more persons or between two or more persons by any means including, but not limited to, emails, telephone conversations, letters, telegrams, teletypes, telexes, telecopies, computer linkups, written memoranda, and face-to-face conversations.

6. "You" means Norman Gitis.

Schedule A: Documents To Be Produced

Request No. 1

All documents that describe the test procedures used to test the FiberWire samples as described in Dr. Gitis' "Comparative Suture Testing" report dated March 23, 2006.

Request No. 2

All technical manuals for all equipment used to test the FiberWire samples as described in Dr. Gitis' "Comparative Suture Testing" report dated March 23, 2006.

Request No. 3

All documents that identify the testing equipment used to test the FiberWire samples as described in Dr. Gitis' "Comparative Suture Testing" report dated March 23, 2006.

Request No. 4

All communications between any of Arthrex, you, Dr. Mukherjee, Dr. Burks, and/or Dickstein, Shapiro, Morin & Oshinsky LLP concerning the lawsuit commenced by the Complaint attached as Exhibit 1.

Request No. 5

All documents and things concerning this lawsuit, including, but not limited to, documents concerning "Comparative Suture Testing" dated March 23, 2006.

Things To Be Produced

Request No. 1

All tested and untested samples referred to in "Comparative Suture Testing" dated March 23, 2006 including but not limited to the spools on which they were wound.

EXHIBIT 14

AO 88 (11/91) Subpoena in a Civil Case

United States District Court

FOR THE NORTHERN DISTRICT OF CALIFORNIA

DePuy Mitek, Inc.,
a Massachusetts Corporation

Plaintiff,

V.

Arthrex, Inc.,
a Delaware Corporation and

Pearsalls Ltd.,
A Private Limited Company
of the United Kingdom,

Defendants.

SUBPOENA IN A CIVIL CASE in the United States District Court for the District of Massachusetts

Case Number: 04cv12457 PBS

TO: **Norman Gitis**
1715 Dell Avenue
Campbell, CA 95008 USA

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case on topics set forth in Schedule A attached hereto. The deposition will be recorded by stenographic means and recorded by video and audio tape, and by instant visual display of the stenographic record.

PLACE OF DEPOSITION	DATE AND TIME
Woodcock Washburn LLP Cira Centre, 12th Floor 2929 Arch Street Philadelphia, PA 19104	July 18, 2007 at 9:00 a.m.

☒ YOU ARE COMMANDED to produce and permit inspection and copying of the documents and things set forth in Schedule A attached hereto at the place, dates, and time specified below:

PLACE	DATE AND TIME
Woodcock Washburn LLP Cira Centre, 12th Floor 2929 Arch Street Philadelphia, PA 19104	July 18, 2007 at 9:00 a.m

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (ATTORNEY FOR PLAINTIFF)	DATE
Angela Verrecchio	7/16/07

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Angela Verrecchio, Woodcock Washburn LLP, Cira Centre, 12th Floor, 2929 Arch St., Philadelphia, Pennsylvania 19104, 215-568-3100

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO 88 (11/91) Subpoena in a Civil Case

PROOF OF SERVICE

	DATE	PLACE
SERVED	July 16, 2006	Dickstein Shapiro LLP 1825 Eye Street, N.W. Washington, D.C. 20006
SERVED ON (PRINT NAME)		MANNER OF SERVICE
Salvatore Tamburo		Facsimile: (202)420-2201
SERVED BY (PRINT NAME)		TITLE
Angela Verrecchio		Attorney

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
Signature of Server

_____
Address of Server

_____

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

© PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for depositions, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy the material or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
(I) fails to allow reasonable time for compliance;
(ii) requires a person who is not a party or an officer of a party to travel to a place

more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(b)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
(iv) subjects a person to undue burden.
(B) If a subpoena
(I) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

Schedule A

Pursuant to Rule 45 of the Federal Rules of Civil Procedure and the Local Rules of the District of Massachusetts, Plaintiff DePuy Mitek, by and through its counsel, will take the deposition upon oral examination of Norman Gitis beginning on July 18, 2007 at 9:00 a.m. at the offices of Woodcock Washburn LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA 19103, USA. The deposition will be conducted before an officer authorized by law to administer oaths and will be recorded by stenographic and video means. The deposition will proceed from day to day, weekends and federal holidays excluded, until completed.

Instructions and Definitions

1. DePuy Mitek has sued Arthrex in the United States District Court for the District of Massachusetts for Arthrex's infringement of U.S. Patent No. 5,314,446. A copy of DePuy Mitek's Amended Complaint is attached as Exhibit 1.

2. "Arthrex" means Arthrex, Inc. and includes each of its predecessors, successors, subsidiaries, divisions, and departments.

3. "FiberWire" means each Arthrex suture that is or have been sold under the tradenames FiberWire or TigerWire.

4. "Concerning" means referring to, relating to, commenting upon, evidencing or embodying.

5. "Communication(s)" means any transmission of information by one or more persons or between two or more persons by any means including, but not limited to, emails, telephone conversations, letters, telegrams, teletypes, telexes, telecopies, computer linkups, written memoranda, and face-to-face conversations.

6. "You" and "your" mean Norman Gitis.

Schedule A: Document Requests

Document Request No. 1

Any documents or information concerning the computer virus alleged to have corrupted the data in your "Comparative Suture Testing" Report dated March 23, 2006.

Document Request No. 2

Any documents or information concerning the declaration executed by you on August 28, 2006 in connection with the lawsuit commenced by the Complaint attached as Exhibit 1.

Document Request No. 3

All documents concerning your "Supplemental Test Report on Comparative Suture Testing (supplement to the test report of March 23, 2006)" dated June 28, 2007.

Document Request No. 4

All communications between any of Arthrex, Pearsalls Ltd., you, Dr. Mukherjee, Dr. Burks, Dickstein, Shapiro, Morin & Oshinsky LLP, or any other person or entity concerning the lawsuit commenced by the Complaint attached as Exhibit 1.

Document Request No. 5

All documents concerning the lawsuit commenced by the Complaint attached as Exhibit 1.

Document Request No. 6

All of Dr. Gitis's invoices or bills for work that Dr. Gitis performed in connection with the lawsuit commenced by the Complaint attached as Exhibit 1.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek Inc., **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex Inc.,** **a Delaware Corporation, and** **Pearsalls Limited,** **a Private Limited Company of the United Kingdom,** **Defendant.**	)	**CIVIL ACTION NO. 04-12457 PBS**

UPDATED NOTICE OF DEPOSITION OF NORMAN GITIS

PLEASE TAKE NOTICE THAT, pursuant to Rule 30 of the Federal Rules of Civil Procedure, beginning at 9:00 a.m., on July 3, 2007, Plaintiff DePuy Mitek will take the deposition upon oral examination of Norman Gitis at Woodcock Washburn LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, PA 19104 or at such other location, date and time as may be mutually agreed, before a Notary Public or duly authorized officer authorized to administer oaths. The deposition will be recorded by stenographic means and may also be recorded by video or audio tape, and by instant visual display of the stenographic record.

The deposition will proceed in accordance with the Federal Rules of Civil Procedure and will continue from day to day (Sundays and holidays excluded) until completed unless otherwise agreed.

You are invited to attend and cross-examine.

Date: July 16, 2007

DEPUY MITEK, INC.,
By its attorneys,

Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
Cira Centre, 12th Floor
29292 Arch Street
Philadelphia, PA 19104
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Michelle Chassereau Jackson (BBO 654825)
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604
(617) 439-2000

CERTIFICATE OF SERVICE

I certify that the foregoing DePuy Mitek Inc.'s Updated Notice of Deposition of Norman Gitis was served *via* facsimile on July 16, 2007 on the following:

Charles W. Saber
Dickstein, Shapiro LLP
1825 Eye Street NW
Washington, DC 20006
Fax: (202) 420-2201

Christopher Weld, Jr.
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
Fax: (617) 227-5777

Dated: July 16, 2007

Angela Verrecchio

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff.** **V.** **Arthrex, Inc.** **a Delaware Corporation,** **and** **Pearsalls Limited,** **a Private Limited Company of the United Kingdom** **Defendants.**	)	Civil Action No. 04-12457 PBS **AMENDED COMPLAINT**

COMPLAINT

Plaintiff, DePuy Mitek, Inc. ("DePuy Mitek") for its complaint against Defendants, Arthex, Inc. ("Arthrex") and Pearsalls Ltd. ("Pearsalls") alleges:

PARTIES, JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the United States Patent Laws, Title 35 of the United States Code. This Court has jurisdiction over this action's subject matter under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district under 28 U.S.C. § 1400(b) and §1391.

2. Plaintiff DePuy Mitek is a corporation organized and existing under the laws of the State of Massachusetts and has a principal place of business at 249 Vanderbilt Avenue, Norwood, Massachusetts 02602.

3. Defendant Arthrex is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

4. Defendant Pearsalls is a private limited company organized and existing under the laws of the United Kingdom and has a principal place of business at Tancred Street, Taunton, Somerset TA1 1RY.

CLAIM FOR RELIEF

5. On May 24, 1994, United States Letters Patent No. 5,314,446 ("446 Patent") entitled "Sterilized Heterogeneous Braids" was duly and legally issued by the United States Patent and Trademark Office to Ethicon, Inc. as assignee. Ethicon, Inc. assigned the 446 patent to DePuy Mitek, Inc. A true and correct copy of the 446 Patent is attached as Exhibit A to this Complaint.

6. On information and belief, without license or authorization, Arthrex has been and is infringing claims of the 446 Patent in the United States by making, using, selling, and offering for sale in the United States, including within this judicial district, sutures and sutures having attached needles, anchors, or other products, that are claimed in the 446 Patent, including at least the sutures sold under the trade name FiberWire™. On information and belief, without license or authorization, Arthrex has been and is inducing others to directly infringe the 446 Patent in the United States, including within this judicial district, by inducing distributors to sell and surgeons to use sutures and sutures having attached needles, anchors, or other products, that are claimed in the 446 Patent, including at least the sutures sold under the trade name FiberWire™.

7. On information and belief, Pearsalls has infringed and continues to infringe the 446 Patent by contributing to and inducing Arthrex's infringement of the 446 Patent by

providing Arthrex with sutures that are incorporated into the commercial TigerWire® and FiberWire™ products, which sutures are not a staple article of commerce and have no use other than to practice the invention claimed in the 446 Patent. These sutures and products incorporating the same are sold throughout the United States.

8. On information and belief, Pearsalls has acted in concert with Arthrex to design, develop, and commercialize FiberWire™ and TigerWire® sutures with full knowledge that these products will be sold throughout the United States.

9. On information and belief, Arthrex has known of the 446 patent's existence since at least shortly after its issuance. On information and belief, Arthrex's infringing acts as set forth above have been deliberate, willful, and in reckless disregard of DePuy Mitek's patent rights.

10. On information and belief, Pearsalls has known of the 446 patent's existence since at least shortly after this lawsuit was filed in November 2004.

11. DePuy Mitek has been damaged by Arthrex's and Pearsalls' infringing activities. On information and belief, Arthrex and Pearsalls will continue their infringing activities, and continue to damage DePuy Mitek, unless enjoined by this Court. DePuy Mitek has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff DePuy Mitek respectfully demands judgment for it and against Defendants Arthrex and Pearsalls as follows:

(a) That this Court adjudge that DePuy Mitek owns the 446 Patent and that DePuy Mitek has all rights of recovery under the 446 patent;

(b) That this Court adjudge that Arthrex and Pearsalls have been infringing the 446 patent;

(c) That this Court issue an injunction enjoining Arthrex and Pearsalls and their officers, agents, servants and employees, privies, distributors and all persons in active concert or participation with them from further infringement of the 446 patent;

(d) That this Court ascertain and award DePuy Mitek damages sufficient to compensate it for Arthrex's and Pearsalls' infringement and that the damages so ascertained be trebled and awarded to DePuy Mitek with interest;

(e) That this Court find this case to be exceptional and award DePuy Mitek its attorneys fees, costs and expenses in this action; and

(f) That this Court award DePuy Mitek such other relief as the Court may deem just and proper.

JURY DEMAND

DePuy Mitek demands a jury trail on all issues so triable.

DEPUY MITEK, INC.,

Dated: September 9, 2005

By its attorneys,

/s/ Michelle Chassereau Jackson
Daniel J. Gleason (BBO # 194900)
Michelle Chassereau Jackson (BBO #654825)
NUTTER McCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604
(617) 439-2000

and

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United States Patent [19]

Hunter et al.

[11] **Patent Number: 5,314,446**

[45] **Date of Patent: May 24, 1994**

[54] **STERILIZED HETEROGENEOUS BRAIDS**

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[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

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Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

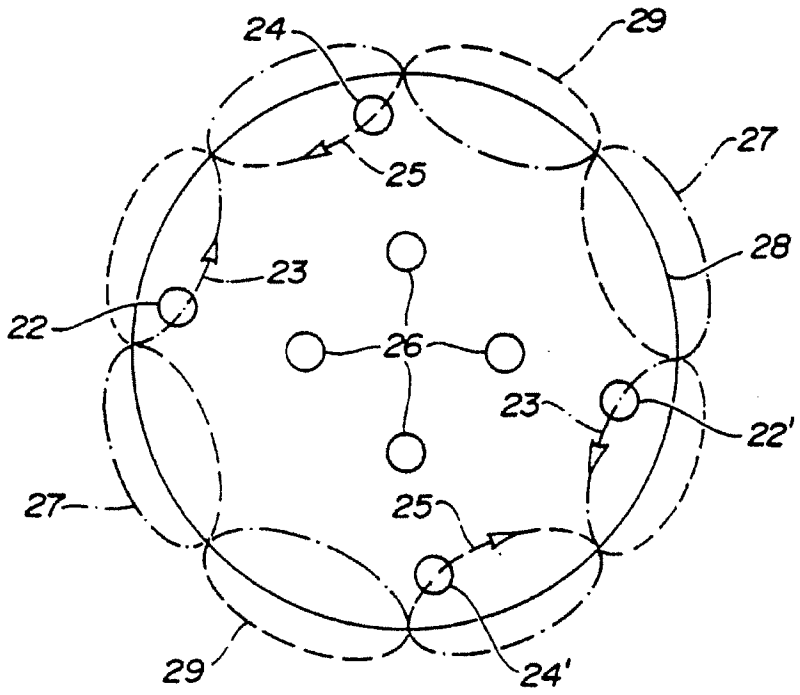


FIG-2

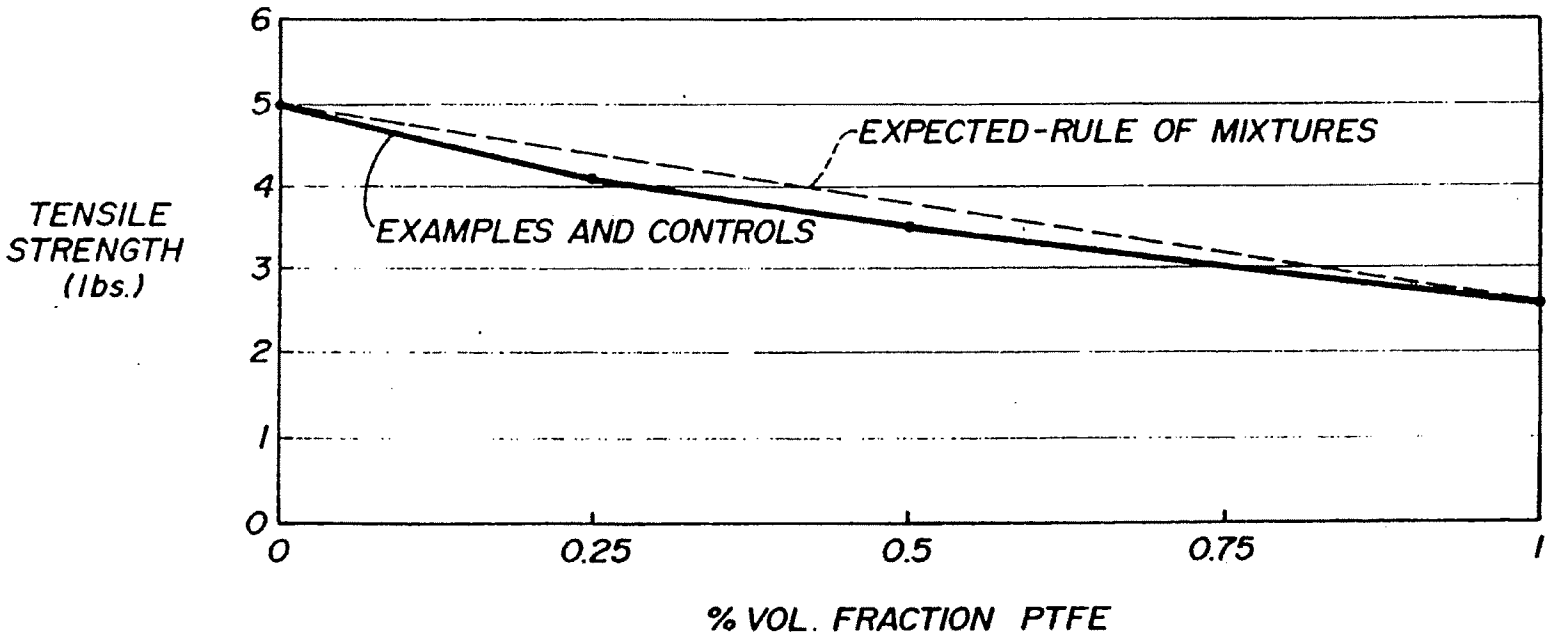
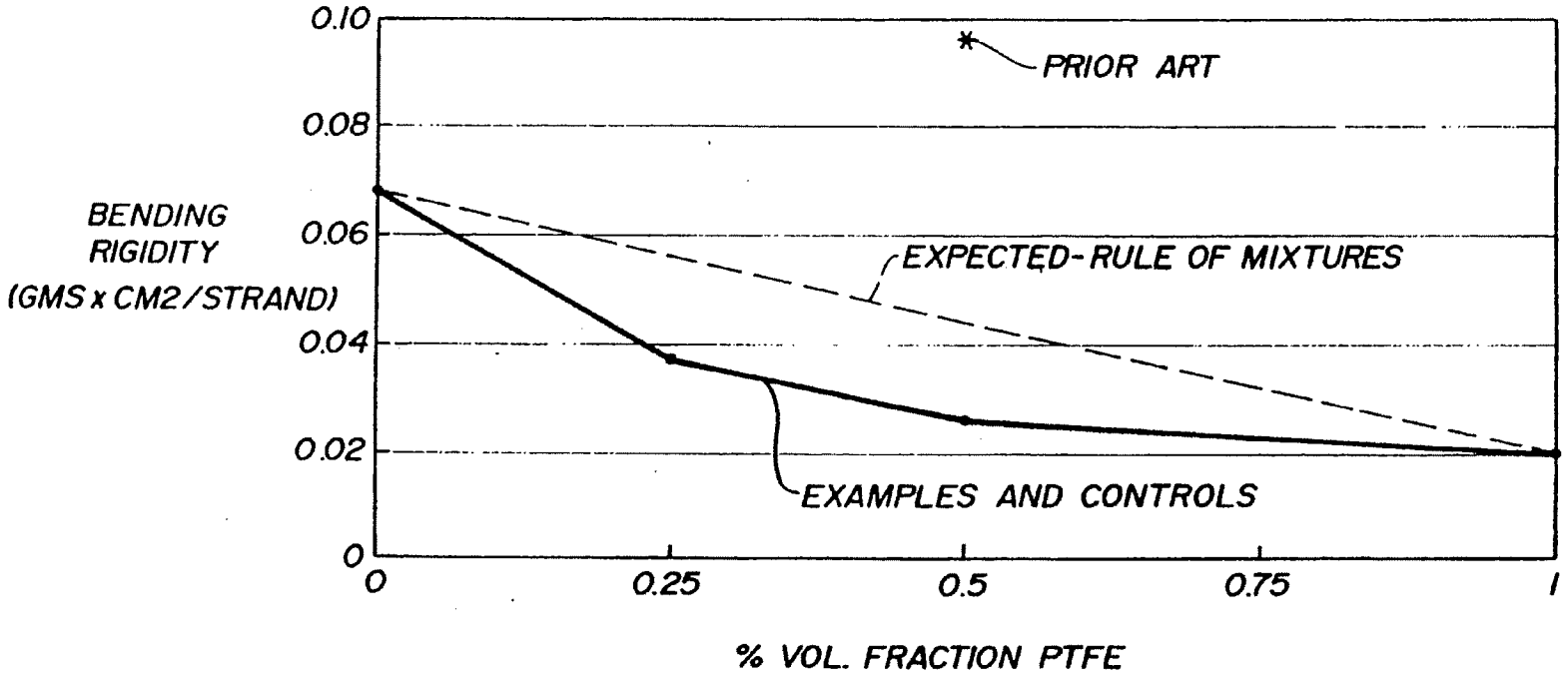

TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


0.10
0.08
0.06
0.04
0.02
0
BENDING RIGIDITY (GMS x CM2/STRAND)
PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c = (Vf_a)(P_a) + (Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff.** **v.** **Arthrex, Inc.** **a Delaware Corporation** **Defendant.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek, Inc.'s First Set of Requests for Document and Things to Arthrex, Inc.

Pursuant to Rules 26 and 34 of the Federal Rules of Civil Procedure, Plaintiff, DePuy Mitek requests that Defendant, Arthrex, Inc. produce for inspection, copying and testing within thirty (30) days, the documents and things set forth below that are in its possession, custody or control, at the offices of Woodcock Washburn LLP, One Liberty Place, 46th Floor, Philadelphia, Pennsylvania 19103.

DEFINITIONS

A. "Patent-in-Suit" means U.S. Patent No. 5,314,446.

B. "Prior Art" means any subject matter described in 35 U.S.C. §102 that Arthrex contends, or may contend, is prior art to the Patent-in-Suit.

C. "Concerning" means relating to, referring to, describing, evidencing, or constituting.

D. "Braided Suture Product(s)" and "Arthrex Braided Suture Product(s)" mean Arthrex's FiberWire™ suture products; any product made, used or sold by either

Arthrex or on behalf of Arthrex that incorporates FiberWire™ sutures, such as by being coupled to, preloaded with, or available with any other another device, such as an anchor or a needle (*e.g.* Arthrex's Corkscrew Suture Anchors, Bio-Corkscrew Suture Anchors, Corkscrew II, Bio-Corkscrew Suture Anchors with needles, FASTak II Suture Anchor, FASTak Suture Anchor with #2 FiberWire, Bio-FASTak Suture Anchor, Bio-SutureTak with #2 FiberWire, FiberStick, 2-0 FiberStick, FiberWire loop with Needle for Needle Punch); any product made, used or sold by either Arthrex or on behalf of Arthrex since 1998 that has a braided suture construction; or any product made, used, or sold by either Arthrex or on behalf of Arthrex since 1998 that includes a braided suture construction coupled to, preloaded with, or available with any other device such as an anchor or a needle.

E. " Convoyed Braided Suture Product(s)" and "Arthrex Convoyed Braided Suture Product(s)" mean any device, product, instrument or accessory that is sold as a result of the sale of any Braided Suture Product or is sold attendant to the sale of a Braided Suture Product.

F. The term "Arthrex" means Arthrex, Inc. and includes each of its predecessors, successors, subsidiaries, divisions, and departments.

REQUESTS

1. Arthrex Organizational charts from May 24, 1994 to the present.

2. Documents sufficient to describe each policy of Arthrex concerning document destruction or document retention from May 24, 1994 to present.

3. All documents and things concerning the Patent-in-Suit, including, but not limited to, the files of any in-house Arthrex attorney regarding the Patent-in-Suit.

4. All documents and things concerning any analysis that concerns the Patent-in-Suit, including but not limited, to analysis relating to infringement, validity, or unenforceability, willful infringement, strength, scope, clearance, or valuation of the Patent-in-Suit or any claim of the Patent-in-Suit.

5. All communications between Arthrex and any person concerning the Patent-in-Suit including, but not limited to, communications with the assignee named on the cover of U.S. Patent No. 5,318,575.

6. All opinions or communications of counsel concerning the Patent-in-Suit and all documents and things concerning such opinions or communications.

7. All documents and things concerning Alastair W. Hunter, Arthur Taylor, Jr. or Mark Steckel.

8. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 9 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

9. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 10 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

10. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 11 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

11. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 12 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

12. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 13 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

13. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 14 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

14. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraphs 15-17 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

15. All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 18 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

16. All documents and things upon which Arthrex relies, or intends to rely, to support its Counterclaim in Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

17. All documents and things upon which Arthrex relies, or intends to rely, to support its denial in Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint that Arthrex's infringement is willful.

18. All Prior Art and all documents and things concerning any Prior Art including, but not limited to, the results of any prior art searches regarding the validity or invalidity of the Patent-in-Suit.

19. All documents and things concerning any Arthrex foreign or United States patent or patent application that describes a braided suture.

20. All documents and things concerning the level of ordinary skill in the art of the Patent-in-Suit.

21. All documents and things that evidence or refute any secondary consideration (including, but not limited to, commercial success, long felt but unresolved need, failure of others, commercial acquiescence, and copying) that concern the nonobviousness or obviousness of the Patent-in-Suit.

22. All documents and things that support or refute any definition, meaning, interpretation, or construction of any term, limitation, word, or element of any claim of the Patent-in-Suit espoused by either party.

23. All extrinsic evidence or material upon which Arthrex relies, or intends to rely, to support any claim construction espoused by Arthrex.

24. All documents and things concerning the operation, performance, material characteristics, or material properties of any Braided Suture Product or part of any Braided Suture Product.

25. Documents sufficient to identify the structure and intended use of each Braided Suture Product and/or each Convoyed Braided Suture Product.

26. All instructions for use and training materials for each Arthrex Braided Suture Product.

27. Documents sufficient to identify the amount of each Braided Suture Product that has been imported into the United States by or for Arthrex and when importation of each Braided Suture Product occurred.

28. Each sales contract for each Braided Suture Product.

29. All documents and things concerning any acquisition or licensing by or from Arthrex of any technology concerning any Braided Suture Product.

30. All documents and things concerning any changes or modifications to the design of any Braided Suture Product since 1998, including documents sufficient to identify the nature of such change or modification and the date such change or modification was made

31. All correspondence between Arthrex and the U.S. Food and Drug Administration or foreign equivalent of the U.S. Food and Drug Administration related to obtaining marketing approval for any Braided Suture Product.

32. All marketing materials, advertisements, press releases, news articles, and Internet web pages, concerning Arthrex's Braided Suture Products.

33. Arthrex's financial statements, business plans, sales plans, and marketing plans concerning any Braided Suture Product.

34. Periodic statements sufficient to describe Arthrex's costs for it Braided Suture Products.

35. Documents and things sufficient to describe the market demand, including market and sales forecasts or surveys, for any Braided Suture Product, including documents concerning the actual or potential size of such market demand in dollars, units, or any other measure.

36. For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all sales of Braided Suture Product including documents sufficient to identify the following information for each Braided Suture Product:

a. name of the product sold;

b. product indicia used by Arthrex to identify the product;

c. number of units sold;

d. total amount of sales in dollars;

e. average per unit price in dollars; and

f. gross and net profits (or losses).

37. Documents sufficient to identify all selling prices and pricing policies for each Braided Suture Product.

38. For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all actual or proposed discounting, or policies concerning the actual or proposed discounting, of any Braided Suture Product.

39. Documents and things that describe any technical advantages of each Braided Suture Product or reasons why customers purchase each Braided Suture Product.

40. Documents and things that reflect Arthrex's market share for its Braided Suture Products on a monthly or quarterly basis since the introduction of Arthrex's Braided Suture Products, including any third party reports and internally created documents, and analysis of the same.

41. All documents and things concerning the date(s) on which and the circumstances under which Arthrex first became aware that DePuy Mitek claimed that any of its patents covered any Braided Suture Product.

42. Documents sufficient to identify any person who has participated in the technical development of any Braided Suture Product (including corporate entities, business partners, engineers, designers, project managers, product managers, marketing mangers, product planners, or patent counsel, whether or not these persons are or were affiliated with Arthrex).

43. Documents concerning the design and development of each Braided Suture Product including but not limited to the files and laboratory notebooks of each engineer or other person who participated in the development of each Braided Suture Product.

44. All documents and things concerning any effort, attempt, or consideration by Arthrex or any other person to avoid infringement of the Patent-in-Suit.

45. All documents concerning the date on which Arthrex first gained actual knowledge of the Patent-in-Suit.

46. All documents and things concerning any decision of Arthrex to select any materials for the suture used in any Braided Suture Product including but not limited to any communications with vendors that state a material preference for Arthrex's Braided Suture Product.

47. All documents and things concerning any policy or procedure of Arthrex concerning patent infringement or non-infringement.

48. All reports that were generated by, or on behalf of, any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

49. All documents and things relied upon or considered by any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

50. All documents and things considered in preparing any response to DePuy Mitek's First Set of Interrogatories to Arthrex Inc., and all documents and things containing information responsive to any of those interrogatories.

51. All customer surveys, market preference tests or surveys, or other studies concerning any Braided Suture Product.

52. Each communication between Arthrex and any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

53. Any patent infringement indemnification or patent insurance agreement that Arthrex is a party to concerning any infringement of any Braided Suture Product.

54. Each license or agreement under which Arthrex has or is paying royalties or consideration for sutures, anchors, needles, or shoulder surgical products, instruments, or technology and royalty reports reflecting payments under any such licenses or agreements.

55. All documents and things concerning whether the selling, licensing, providing or otherwise distributing any Braided Suture Product affects the sales of other Arthrex products and/or services.

56. Documents sufficient to identify the structure, identity and use of any product that is sold by Arthrex as a result of or is associated with the sale of any Braided Suture Product.

57. For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all actual sales of each Convoyed Braided Suture Product including documents sufficient to identify the following information for each Convoyed Braided Suture Product:

a. name of the product sold;

b. product indicia used by Arthrex to identify the product;

c. number of units sold;

d. total amount of sales in dollars;

e. average per unit price in dollars; and

f. gross and net profits (or losses).

58. All documents that support, contradict, or otherwise relate to Arthrex's admissions, denials or other allegations set forth in paragraphs 9-18 of Arthrex's Answer and paragraphs 6-8 of its counterclaim.

59. All documents concerning any comparisons between any Braided Suture Product and any other product it competes with in the marketplace.

60. All communication(s) with any non-party about this lawsuit.

61. All documents that identify Arthrex's supplier(s) of materials or components for use in each Braided Suture Product.

62. All documents that describe the tensile strength of any suture used in any Braided Suture Product with and without a coating and how the tensile strength was determined.

63. All documents that describe the bending strength and rigidity of any suture used in any Braided Suture Product with and without a coating and how that bending strength and rigidity was determined.

64. All documents concerning how Arthrex defines knot slippage and knot tiedown and the procedures that Arthrex's uses to determine them.

65. All documents concerning the knot slippage tests set forth in Mr. Soffen's February 20, 2004 letter to Mr. Skula, how the knot slippage was determined, why it was determined, and who decided to determine it.

66. All documents that identify who was involved in the tests set forth in Mr. Soffen's February 20, 2004 letter to Mr. Skula.

67. Documents sufficient to describe the manufacturing process used to manufacture each Braided Suture Product, including but not limited to, manufacturing specifications and the manufacturing steps or processes taken to manufacture each Braided Suture Product.

68. All documents concerning the nature of and the reasons for each coating used on each suture part of each Braided Suture Product.

69. All documents concerning the testing of any Braided Suture Products that have a coating, including documents concerning the suture's tensile strength, knot-slippage properties, and bending strength and rigidity.

70. All document that support any damages claim by Arthrex including but not limited to its trial counsel's hourly rates for attorneys that worked on this litigation, bills for this lawsuit, and any agreement concerning counsel fees for defending this lawsuit.

Things To Be Produced

1. A sample of each Braided Suture Product.

2. A sample of each Convoyed Braided Suture Product.

3. A sample of each Braided Suture Product without a coating but otherwise in its final manufacturing state (*i.e,* having all manufacturing process completed other than those associated with the coating).

Date: 1/14/05

DEPUY MITEK, INC.,

By its attorneys,

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CERTIFICATE OF SERVICE

I certify that the foregoing DePuy Mitek's First Set of Requests for Document and Things to Arthrex, Inc. was served by facsimile on the following on January 14, 2005:

Charles W. Saber
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Dated: January 14, 2005

Erich Falke

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S RESPONSE TO DEPUY MITEK'S DRAFT PROPOSED STIPULATED FACTS OF JUNE 29, 2007

Stipulated Fact #1

DePuy Mitek owns U.S. Patent No. 5,314,446 and has owned it since August, 2004 (DMI000338-340).

OBJECT -- ownership of '446 patent being contested

Stipulated Fact #2

Ethicon, Inc. owned U.S. Patent No. 5,134,446 from May 24, 1994 until August, 2004 (446 Patent; DMI000338-340).

OBJECT -- ownership of '446 patent being contested

Stipulated Fact #3

Arthrex, Inc. received actual notice of U.S. Patent No. 5,134,446 on December 1, 2003 (J. Schmeiding 1/5/06 Dep. at 64:12-15).

OBJECT – irrelevant – goes to willfulness

Stipulated Fact #4

FiberWire and TigerWire are surgical sutures (FiberWire IFU)(Undisputed Mitek Fact #11; Arthrex Response to Mitek Request to Admit No. 3).

AGREE

Stipulated Fact #5

Pearsalls manufactures FiberWire and TigerWire (Grieff Dep. at 12:2-11; 12:18-23; 16:24-17:3; 17:9-12).

OBJECT – Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #6

FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 279 (Hallett 1/11/2006 Dep. at 12:21-13:9; 13:15-19).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #7

FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 281 (Hallett 1/11/2006 Dep. at 14:8-16; 19:10-13).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #8

Pearsalls has imported unsterilized FiberWire and TigerWire into the United States (Grieff Dep. at 20:10-22).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #9

Pearsalls has sold unsterilized FiberWire and TigerWire in the United States to R.K. Manufacturing (Grieff Dep. at 20:10-22).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #10

RK Manufacturing does nothing to alter the construction of the braid it receives from Pearsalls and sells to Arthrex (Ponton Dep. at 74:16-21).

OBJECT – "alter the construction" is undefined, confusing and misleading

Stipulated Fact #11

RK Manufacturing has sold sterilized FiberWire and TigerWire to Arthrex, Inc. within the United States (Grieff Dep. at 37:23-38:8).

AGREE

Stipulated Fact #12

Arthrex, Inc. sells FiberWire and TigerWire in the United States (ARM 3355)(Undisputed Mitek Fact #51).

AGREE

Stipulated Fact #13

For all FiberWire and TigerWire products sold outside of the United States, Arthrex, Inc. supplies those products from the United States. (Grieff Dep. at 70:16-24; 71:1-5, 6; 13-17).

OBJECT – irrelevant

Stipulated Fact #14

Arthrex, Inc. sells FiberWire and TigerWire sutures attached to a needle (DMI Ex. 5 at ARM 001469).

AGREE

Stipulated Fact #15

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-

1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 101)(Undisputed Mitek Fact #26).

AGREE

Stipulated Fact #16

Arthrex's sells the following FiberWire and TigerWire suture product codes within the United States: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (ARM 3355).

AGREE

Stipulated Fact #17

FiberWire sutures and TigerWire sutures sold by Arthrex are sterilized (Arthrex Response to Mitek's Request to Admit No. 3)(DMI Ex. 3 at 13-1).

AGREE

Stipulated Fact #18

The cover in FiberWire suture is constructed of ultra high molecular weight polyethylene (UHMWPE) and polyethylene terephthalate (PET) (Arthrex Response to Mitek's Request to Admit No. 9).

AGREE

Stipulated Fact #19

FiberWire is a heterogeneous braid composed of a first and second set of continuous and discrete yarns (Mukherjee Dep. at 362:1-4)(Undisputed Mitek Fact #13).

OBJECT – incorrect – FiberWire *includes* a heterogeneous braid composed of a first and second set of continuous and discrete yarns

Stipulated Fact #20

FiberWire includes a set of PET yarns made up of a plurality of PET filaments (Dreyfuss Dep. at 64:14-17).

AGREE

Stipulated Fact #21

Each FiberWire suture product has PET as a second set of yarns (*id*.)(Undisputed Mitek Fact #49).

OBJECT – confusing attempt to reference claim language – no context

Stipulated Fact #22

FiberWire has each yarn from the second set composed of a plurality of filaments of a second fiber-forming material of PET (Mukherjee Dep. at 363:7-16)(Undisputed Mitek Fact #46).

OBJECT – confusing attempt to reference claim language – no context

Stipulated Fact #23

FiberWire includes a set of UHMW PE yarns made up of a plurality of UHMW PE filaments (Dreyfuss Dep. at 50:21-51:1)

AGREE

Stipulated Fact #24

In FiberWire, at least one yarn of ultra high molecular weight PE is in direct intertwining contact with a PET yarn (Dreyfuss Dep. at 50:21-51:1).

AGREE

Stipulated Fact #25

FiberWire is a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction (Mukherjee Dep. at 362:5-8)(Undisputed Mitek Fact #13).

OBJECT – incorrect – FiberWire *includes* a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction

Stipulated Fact #26

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id*. at 362:1-4)(Undisputed Mitek Fact #15).

AGREE

Stipulated Fact #27

The ultra high molecular weight polyethylene yarns in FiberWire and Tiger Wire are continuous and discrete (*id.*)

AGREE

Stipulated Fact #28

The PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET (Dreyfuss 9/16/05 Dep. at 64:14-17)(Undisputed Mitek Fact #17).

AGREE

Stipulated Fact #29

No. 2 FiberWire suture, No. 5 FiberWire, No. 0 FiberWire suture, the No. 2-0 FiberWire suture, and the 3-0 FiberWire suture are braided using the same process (Dreyfuss 9/16/05 Dep. at 38:20-24)(Undisputed Mitek Fact #23).

AGREE

Stipulated Fact #30

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (DMI Ex. 318)(Undisputed Mitek Fact #47).

AGREE

Stipulated Fact #31

The purpose of the nylon marking strand in Arthrex's TigerWire product is visual identification (Dreyfuss 12/7/05 Dep. at 74:21-23)(Undisputed Mitek Fact #39).

OBJECT – irrelevant – Defendants not making distinction between FiberWire and TigerWire for purposes of this trial

Stipulated Fact #32

Notwithstanding the color of the yarns, TigerWire's yarns are identical to FiberWire's yarn with the exception that one PET yarn is replaced by one nylon yarn (DMI Ex. 318)(Undisputed Mitek Fact #9).

AGREE

Stipulated Fact #33

TigerWire is braided in the same way as FiberWire (Dreyfuss 9/16/05 at 31:24–32:2)(Undisputed Mitek Fact #10).

AGREE

Stipulated Fact #34

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Brookstein Op. Expert Rpt. at ¶49; DMI Ex. 318)(Undisputed Mitek Fact #50).

AGREE

Stipulated Fact #35

FiberWire size 4-0 does not have a core (*id*. at 55:21-23)(Undisputed Mitek Fact #25).

AGREE

Stipulated Fact #36

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id*. at 104:17-105:9)(Undisputed Mitek Fact #24).

AGREE

Stipulated Fact #37

Ultra-high molecular weight polyethylene is a lubricious material (*id*. at 52:24-53:1)(Undisputed Mitek Fact #29).

OBJECT – no context given

Stipulated Fact #38

Tevdek is a 100% braided polyester suture (Sluss Dep. at 35:17-22; *See* Grafton Dep. at 36:17-18).

AGREE

Stipulated Fact #39

The initial FiberWire prototype was 100 percent ultra-high molecular weight polyethylene (Grafton Dep. at 51:15-17)(Undisputed Mitek Fact #27).

OBJECT – "initial FiberWire prototype" undefined and also irrelevant

Stipulated Fact #40

When developing FiberWire, Arthrex considered a 100% ultra high molecular weight PE braid before it considered braiding ultra high molecular weight PE with PET (Grafton Dep. at 51:15-17)(Undisputed Mitek Fact #139).

OBJECT – irrelevant

Stipulated Fact #41

The knot slippage of the 100% ultra-high molecular weight polyethylene suture was poor because of the lubricity of polyethylene (*id*. at 53:2-5)(Undisputed Mitek Fact #29).

OBJECT -- irrelevant

Stipulated Fact #42

The knot security of the initial FiberWire prototype made from 100 percent ultra-high molecular weight polyethylene was poor (*id*. at 51:4-7; 53:20-23)(Undisputed Mitek Fact #30).

OBJECT -- irrelevant

Stipulated Fact #43

Mr. Grafton's idea was to add the PET and to improve the knot security of the suture (Undisputed Mitek Fact #30)(*id*. at 53:24-54:5).

AGREE

Stipulated Fact #44

The FiberWire prototype suture that included PET braided with ultra-high molecular weight polyethylene had good knot security (*id*. at 54:24-55:1)(Undisputed Mitek Fact #31).

AGREE

Stipulated Fact #45

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 282, underwent all FiberWire manufacturing processes prior to the wind to skein process and the scouring process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 33:3-34:7; 36:16-18).

OBJECT – irrelevant

Stipulated Fact #46

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 283, underwent the FiberWire braiding process and all FiberWire manufacturing processes that are before the braiding process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 35:10-13; DMI Ex. 279).

OBJECT -- irrelevant

Stipulated Fact #47

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 284, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes that are before the dying process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 36:1-4; 36:19-12; DMI Ex. 279).

AGREE

Stipulated Fact #48

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 285, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process (Hallett 1/11/2006 Dep. at 37:10-13; DMI Ex. 279).

AGREE

Stipulated Fact #49

The FiberWire sample, denoted as DePuy Mitek Deposition Exhibit 342, under went all of the manufacturing process in DePuy Mitek Exhibit 279 before the stretching and coating

processes, and once coated, stretched, and heated a single time (Hallett 1/12/2006 Dep. at 349:7-13; 350:1-5).

OBJECT – irrelevant and confusing

Stipulated Fact #50

Pearsalls' "dye stage" testing occurs after the dying and scouring process but before the winding, stretching and coating, and final inspection/measuring processes (Hallett 1/11/2006 at 47:24-48:3; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #51

Pearsalls' "intermediate" testing occurs after the stretching and coating processes in Mitek deposition Ex. 279 but before the final inspection/measuring processes (Hallett 1/11/2006 Dep. at 49:14-16; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #52

Pearsalls' final stage measuring test occurs after the stretching and coating processes in Mitek deposition Ex. 279 and when Pearsalls' has completed manufacturing the product (Hallett 1/11/2006 Dep. at 53:18-25; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #53

There should not be any construction or manufacturing difference between FiberWire samples from the same batch that are tested at Pearsalls' intermediate and final tests (Hallett 1/11/2006 Dep. at 54:1-6; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #54

DePuy Mitek Deposition Exhibit 316 sets forth specification tolerances for FiberWire (Hallett 1/12/2006 at 237:9-11; 240:21-24).

OBJECT – irrelevant and incorrectly describes document

Stipulated Fact #55

DePuy Mitek Deposition Exhibit 317 sets forth specification acceptance criteria for FiberWire (Hallett 1/12/2006 Dep. at 241:15-18).

AGREE

Stipulated Fact #56

DePuy Mitek Deposition Exhibit 318 is a matrix for the developmental and commercial FiberWire and TigerWire products (Hallett 1/12/2006 Dep. at 245:21-25).

OBJECT – irrelevant and confusing

Stipulated Fact #57

Pearsalls' batch records were generated in the normal course of Pearsalls' business (Hallett 1/12/2006 Dep. at 269:5-11).

AGREE

EXHIBIT 17

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

HIGHLY CONFIDENTIAL

CONFIDENTIAL - NON-PATENT ATTORNEY'S EYES ONLY

deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

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MR. TAMBURO: These are -- I just wanted to produce over to you today the specifications that accompany -- or that are identified in the manufacturing flowchart and FiberWire -- they are not Bates stamped today, but these are all of the specs that are identified in the flowchart. What we will do is make a production to you today so you can use it for the deposition in the next two days, and we will produce a Bates-stamped copy once I get back to the office. That is item number 1.

MR. BONELLA: Thank you.

MR. TAMBURO: You are welcome. Item number 2, what I am going to hand to you is a five-meter length of sample FiberWire material, PS05T2, which was the -- it is a coated sample which was the actual sample used in the February 2004 -- I think it was February 2004 -- tests that were done at Arthrex. We have checked, and there is no uncoated samples remaining, so what we have here is a five-meter portion of the coated, actual samples, and it is a supplement that was asked for, and I told Angela that we could give it to you today.

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MR. BONELLA: Okay.

MR. TAMBURO: So, that is item number 2, and what we will do is; I will identify the Bates number for that when I get back to the office and I will let you know what that is.

There are four more items here. They are US2 FiberWire samples, all of them. They were taken from production from various stages of production, and item number 1 is going to be US2 -- I should say item number 3 produced today, is going to be US2 FiberWire M/C state before scoured, and it is a little capsule including the sample of the suture.

Item number 4 for production today is going to be a similar capsule of suture from a further stage of development which would be US2 FiberWire, M/C state, scoured. That is how it is labeled. And again, I will identify the Bates stamp for that when I get back to the office.

Item number 5 for production today would be another capsule of FiberWire suture, and at further stage of development which would be US2 FiberWire, M/C state, scoured/dyed. This has been dyed, and again, I will identify the Bates number for that sample when I get back.

The last item today for production is a US2 FiberWire M/C state dyed/coated. It is the fourth capsule of suture, and I will identify the Bates stamp when I get back to the office. Thank you.

MR. BONELLA: I am going to show you, Mr. Hallett, DePuy Mitek Exhibit 279. It has a number on it. You may be familiar with these. These are numbers that the attorneys put on each page of the documents that are exchanged between the parties to identify them, so we can have a way to refer to them, and this number has a -- this page, the DePuy Mitek Exhibit 279 has what we -- we call these, "Bates numbers" -- it is Bates number PR 08324. I made a mark on it here, but I will ask you if you recognize Exhibit 279.

(DePuy Mitek Exhibit 279 marked for identification)

A Yes.

Q What is Exhibit 279?

A It is a flowchart of FiberWire and TigerWire.

Q Flowchart for the manufacturing of FiberWire and TigerWire?

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A Hmm hmm.

Q "Yes"?

A Yes.

Q Is this the current manufacturing flowchart for FiberWire and TigerWire?

A Yes.

Q Have there been previous versions of this flowchart?

A No.

Q No?

A No.

Q Ever, for all time, FiberWire has been manufactured commercially according to Exhibit 279?

A No. Not that I am aware of.

Q Let me make sure that the question is clear. The question is; for all time, has FiberWire been manufactured according to the processes set forth in Exhibit 279?

A Yes.

Q Yes it has?

A Yes.

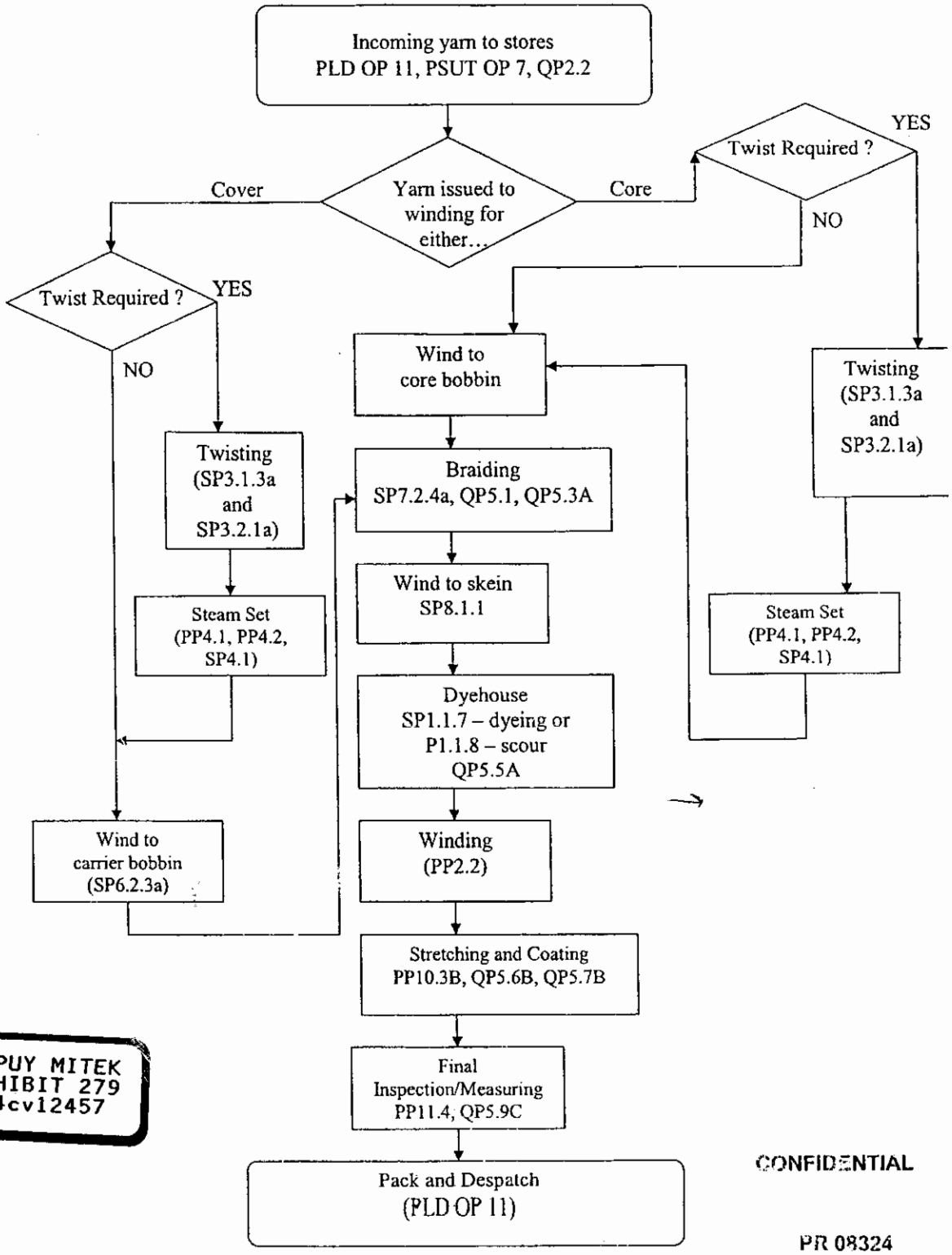
Q Next, I am going to show you DePuy Mitek Exhibit 281.

(DePuy Mitek Exhibit 281 marked for identification)

A Yes.

Pearsalls Sutures

Fibrewire/Tigerwire Flowchart



DEPUY MITEK
EXHIBIT 279
04cv12457

CONFIDENTIAL

PR 08324

EXHIBIT 18

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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deposition of:

BRIAN HALLETT

taken at:
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Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

MR. BONELLA: What do you mean by that?
MR. TAMBURO: -- but I take you at your word that this is the 30(b)(6) portion of the deposition, and again, to the extent that this testimony you are requesting right now is duplicative of testimony that was already given by Pearsalls in the past for this topic, topics number 4, 5, 6 and 7 of the original notice, Arthrex and Pearsalls are objecting to the duplicative testimony requested.
MR. BONELLA: Let's just move on. We will resolve it later. Exhibit 280. Do you recognize that, Mr. Hallett?
A I recognize it as it is.
Q What is Exhibit 280?
A It is a result of a batch of US2 FiberWire.
Q Exhibit 280 is batch testing results?
A Hmm hmm.
Q The tests describe in Exhibit 280 are, those tests that are run in the standard, ordinary business of Pearsalls?
A Correct.
Q Do you see the test at the intermediate stage?

A Yes.
Q Can you label in the manufacturing flowchart where that test was done? Can you label that as the intermediate stage? Okay. So, where you have labeled Exhibit 280 interim/stage on Exhibit 279 reflects the intermediate stage testing done in Exhibit 280?
A Yes.
Q If you could identify -- there is a measure stage testing in Exhibit 280; correct?
A Hmm hmm.
Q Could you label on Exhibit 279 where the measure stage testing is?
A So, do you want me to put the --
Q If you could just put, "Measure stage"? "Exhibit 280 measure stage", and there is also the stretch stage. Would you label where that is in Exhibit 279? And there is also the dye stage testing. Could you label where that is in Exhibit 279? Exhibit -- you have labeled in Exhibit 279, "Exhibit 280 dye stage", and that refers to the dye stage testing in Exhibit 280?
A Yes.
Q The dye testing that is done in Exhibit 280, is that all -- is that of samples of FiberWire

that have undergone the dyeing and scouring processes and all processes before that?
A Yes.
Q You have labeled Exhibit 280, "Stretch stage"?
A Hmm hmm.
Q On Exhibit 279; correct?
A Yes.
Q The samples -- I am sorry, the stretch stage testing that is in Exhibit 280, does that undergo the stretching in all processes before that?
A Yes.
Q The samples that have gone -- that are stretch-tested in Exhibit 280 -- I am sorry, I will rephrase the question. The samples that have been stretch-tested as reflected in Exhibit 280 have not been coated. Is that correct?
A No.
Q "No", it is not correct?
A No. It is not correct.
Q The samples that have been stretch test -- I am sorry, the samples that are tested at the stretch stage have undergone the stretching and coating processes?
A Yes.

Q Are you sure about that?
A Repeat the question again.
Q Sure. The stretch testing, samples that are tested at the stretch stage as in Exhibit 280, have they undergone the stretching and coating processes that are reflected in Exhibit 279?
MR. TAMBURO: Asked and answered, objection.
MR. BONELLA: Mr. Tamburo is going to object to questions, but unless he instructs you not to answer you have to answer the question.
A Yes.
Q The intermediate stage testing, have those samples been stretched and coated?
A Yes.
Q What is the difference between the intermediate stage testing and the stretched stage testing samples?
A They are tested before they are actually coated.
Q Which are tested before they are coated?
A The yarn. The braid.
Q The samples that are tested during the stretched stage, have they been stretched?

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A No.
Q The samples that are tested during the coating -- I am sorry -- the samples that are tested during the stretched stage, have they been coated?
A No.
Q So, that is different to the way you testified before.
A Yes. You have confused me.
Q Let me make sure we have it right. The samples that are tested at the stretched stage, what processes have they undergone in Exhibit 279?
A They are tested before they are stretched.
Q All processes prior to stretching?
A Yes.
Q The samples that have been tested during the stretched stage have not been coated; correct?
A Correct.
Q Intermediate stage, the samples that are tested during the intermediate stage --
A Which has been coated.
Q They have been coated?
A Yes.
Q Coated or stretched?
A Stretch-coated. We don't -- it is just a term. What we call a, "Pad stretch".

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MR. TAMBURO: Excuse me, if I can just interrupt? Can we take a quick break and maybe get this straightened out? I am sure -- I think there is a little bit of inconsistent information, so we just want to make sure we get the correct information. Take a five-minute break?
MR. BONELLA: Yes.
(10.10 am)
OFF THE RECORD
(10.12 am)
MR. BONELLA: Before we broke we were discussing Exhibit 280 where the testing was done with reference to Exhibit 279. Let's go back to the stretched stage testing.
A Okay.
Q The samples that are tested during the stretched stage testing on Exhibit 280, what processes have they undergone as set forth in Exhibit 279?
A The stretched stage is where -- those figures there are where the machine operator was setting up the machine.
Q Setting up what machine?
A Setting up the coating and stretching of

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the machine. This is the preliminary figures that they, the operator, has actually taken.
Q The stretched stage?
A Hmm hmm.
Q The samples that are tested during the stretched stage, have they been stretched and coated?
A Yes.
Q They have been?
A Yes.
Q And the samples that are about the dye stage, they have not been stretched and coated, right?
A Not at the dye stage, no.
Q The intermediate stage, have they been stretched and coated?
A Yes.
Q What is the difference between the intermediate stage and the stretched stage?
A The stretched stage is where the machine operator has set the machine up to make sure they are online for whatever size they are stretching. They do a preliminary test before they set the machine going, set the machine -- to make sure that the machine is set up right, correct.

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Q So, the samples that are tested at the stretched stage and the intermediate, they have both been stretched and they have both been coated?
A Yes.
Q And the difference is that the stretched stage samples are just kind of a preliminary stage where the coated stage is representative of the rest of the batch?
A Absolutely right.
Q What is the purpose of the stretched stage coating test?
A To make sure that the machine is set up correctly, yes.
Q What was different than to Mr. Sonner's (Phonetic) testimony from the last deposition.
MR. TAMBURO: I don't know if it is or isn't.
MR. BONELLA: Exhibit -- and then the final stage measuring test?
A The final stage measuring test is when the product has been completed. It is on final reel, it is sent to the lab for testing.
Q The samples that are tested, the final inspection stage, have been stretched and coated?
A Yes.

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Q What is the difference between the samples that are stretched at the intermediate and the samples that are tested at the final stage?
A There should not be any, but it is a test that we do to make sure that nothing has been upset, if you like, at final measuring.
Q All right. I am ready to start walking around, if you guys are ready. We would like, if possible, if we could try to, if we could walk around with a couple of the exhibits, 279, I think it would be helpful, we will take both copies, and Exhibit 280, if we could walk around with those, and maybe start with Exhibit 279, if you could lead us to the -- I guess wherever would be the point at the beginning of the process.
A Yes.
Q Wherever you feel that would be the best point to demonstrate how it is manufactured.
A Hmm hmm.
Q Great.
(10.16 am)
OFF THE RECORD
(Deposition resumes during tour of facility)
(10.20 am)
A This is our Quality Control Lab. All our

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incoming products, yarns, are tested in here. This is some of the stuff at the moment waiting to be tested, or preparing to be tested. The PET is tested before we use it. From there it goes to packing, production, ready for processing.
Q This room here is the -- where the coming-in yarns are inspected?
A Yes.
Q And the processes in Exhibit 279, in the incoming yarn stores, blocked, are they -- are those processes taking place in the quality testing laboratory here?
A Yes. Correct.
Q These boxes over here are the incoming yarns and this is an example of the Dyneema that is used in FiberWire?
A Correct. These have been tested and have been quality-controlled, so therefore each one is now ready to go into the processing.
Q Okay, and what happens after that?
A From there, it has been -- it goes to the first stage which is twisting of the product.
Q Twisting for the core cover?
A Yes.
Q Where does that take place?

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A Over to the left of us.
MR. BONELLA: If we could proceed to there?
(10.22 am)
(OFF THE RECORD)
(10.23 am)
MR. BONELLA: Mr. Hallett, we just looked at the machine that does the twisting for the FiberWire, right?
A Right.
Q And we saw the core, we saw the ultra high molecular weight polyethylene and yarn being twisted for the covers, right?
A Correct.
Q That was being twisted for the holding twist for the cover?
A Correct.
Q That was Number 2 FiberWire?
A Correct.
Q Pearsalls was not currently doing any twisting for the core; correct?
A Not at this moment in time.
Q Pearsalls were using the same machine to twist the core; correct?
A Correct.

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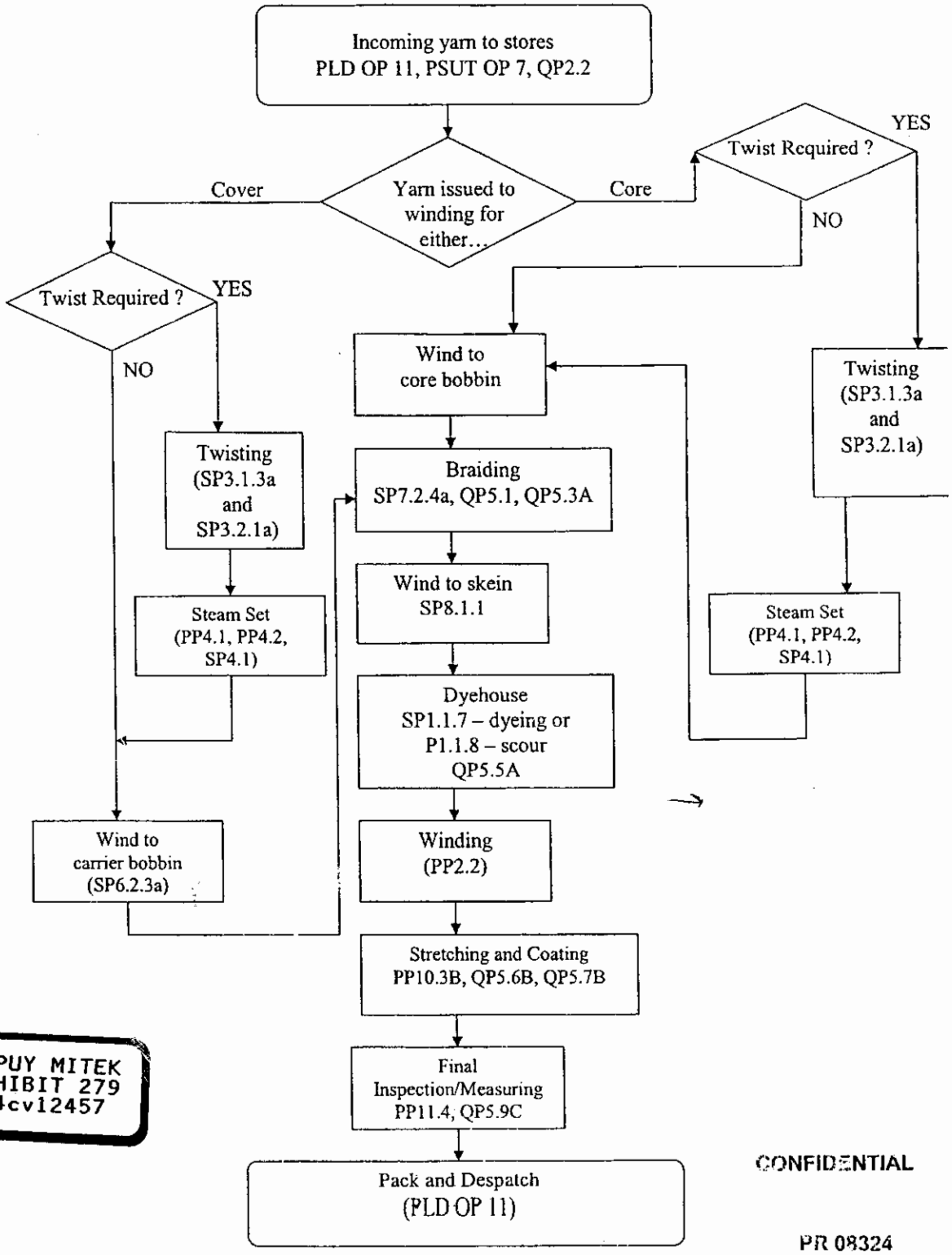
Q The difference being how the machine is set for twisting for one core or another?
A Correct, yes.
Q Is that machine for twisting used for the PET?
A We don't twist the PET.
Q Right. Now, after the twisting processes, there is a steam set process for the core but not the cover; correct?
A Correct.
Q Through here is the steam setting for the --
A No. This is the room from when it has been steam set, it is when it goes from bobbin to core bobbin, core processing bobbin. It comes from a twisted bobbin to a core processing bobbin.
Q A core processing bobbin? And so this is where it has been wound from the twisting would be into a core processing bobbin here?
A Correct. I can show you a bobbin that is being wound at the moment.
MR. BONELLA: That would be great.
(10.26 am)
(OFF THE RECORD)
(10.28 am)

Pearsalls Sutures

Fibrewire/Tigerwire Flowchart



DEPUY MITEK
EXHIBIT 279
04cv12457

CONFIDENTIAL

PR 08324

EXHIBIT 19

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

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Q It is Bates number ARM 2554. It is entitled, "Pearsalls Sutures, FiberWire Process Flowchart", and I will ask if you recognize Exhibit 281.
A Yes.
Q Yes?
A Yes.
Q What is Exhibit 281?
A It is a FiberWire flowchart.
Q It is a manufacturing -- Exhibit 281 is a Pearsalls manufacturing flowchart for FiberWire?
A Yes. It is one of the earlier stages.
Q Exhibit 279 differs from Exhibit 281; correct?
A Yes. The other one just gives more information.
Q Was there a difference in the way FiberWire was manufactured, or is it that the Exhibit 281 just is a simplified version of Exhibit 281?
A Yes. On this one, the 08324, it shows that we have twisted the cover. Previously we never used a twisted cover.
Q At what point did Pearsalls begin twisting the cover for FiberWire manufacturing?

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A I would say about two to three months after we started production.
Q Somewhere in late 2001?
A Yes.
Q Other than twisting the cover, is there any other differences between the way FiberWire has been manufactured over the time period?
A The core was steam set.
Q It was steam set?
A Afterwards.
Q After what?
A After this -- this is the first -- one of the first processes.
Q By, "This", you are referring to Exhibit 281?
A Yes. 281.
Q When you say, "It was steam set", where are you referring to in the procedure that FiberWire was steam set during the manufacturing process?
A The core was steam set.
Q Was that in the earlier versions or later?
A No, later.
Q Later.
A As you can see, the difference is on the flowchart.

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Q Right. So, that steam set for the core, is that in Exhibit 279 but not 281; correct?
A Yes.
Q When did Pearsalls begin steam setting the core in manufacturing FiberWire?
A I think I believe it was about two months afterwards.
Q After --
A We started producing.
Q Sometime -- so, Pearsalls began steam setting the core during the manufacturing process for FiberWire sometime in late 2001?
A Yes.
Q How about for the cover? Was the cover originally steam set as well?
A No.
Q No. When did Pearsalls begin steam setting the cover for the manufacturing process?
A That part, we did not steam set it.
Q You, Pearsalls, has never steam set the cover during the manufacture of FiberWire?
A No. There is no need to. That part of the flowchart is wrong, there.
Q There is also that of the manufacturing processes that are on the flowchart that are called

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out by numbers. Is that right?
MR. TAMBURO: Which flowchart?
MR. BONELLA: Both of them. 279 and 281, right? Some of them, some of the numbers are the same on each flowchart, and some are different. Just a little bit. For example, under the twist of the core on Exhibit 279 it refers to SP3.1.3a and SP3.2.1a, and in Exhibit 281 it refers to SP3.2.1 and SP3.2.2. Do you see that?
A Hmm hmm.
Q Are those different versions of the same procedure?
A Yes.
Q The procedure for the twisting of the cores has changed over time for FiberWire?
A No.
Q Do you know the difference in the versions?
A I believe the actual -- that refers to the processing of the twisting product.
Q Right. My question is; the SP3.2.1a, is it substantially different in any way than SP3.2.1?
A I don't think so, no.
Q I am sorry. Let me just finish the

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question. Is SP3.2.1 and SP3.2.2 substantially different in any way than SP3.1.3a and SP3.2.1a?
MR. TAMBURO: Object to the form.
MR. BONELLA: You can answer the question.
Q I would also like to show you -- the only -- is there anything else wrong about the flowchart in Exhibit 279, other than the block that specifies steam-setting the cover?
A Not that I can see.
Q Exhibit 279 and Exhibit 281 are identified as both processes for manufacturing flowchart, or manufacturing FiberWire. Are there any other flowchart versions that describe the manufacturing processes for FiberWire at any point in time?
A There could be.
Q For example, if you look at the bottom of Exhibit 279, it says that the QSM4.8.27, is that a reference to the -- well, what is that a reference to?
A If you look at the bottom, there is, like, Issue 2 and Issue 6, so, therefore, it has been upgraded six times.
Q The manufacturing process?
A Yes.
Q The manufacturing process for FiberWire

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has had six different --
A Six different version.
Q And the latest one, Exhibit 279, the one that has been in existence since August 5th, 2005?
A Yes.
Q The processes called out in Exhibit 279 are the ones that have been used to manufacture FiberWire since August 5th, 2005?
A Yes.
Q Exhibit 281 are manufacturing processes that were used to make FiberWire beginning on January -- I am sorry, June 29th, 2001?
A Hmm hmm, yes.
MR. TAMBURO: I think that other date was May 8th, Mike, because I think the European -- on Exhibit 279, I think you said, "August 5th". I think it is actually May 8th, 2005.
MR. BONELLA: Thank you. Exhibit 279 reflects the manufacturing processes that have been used to manufacture FiberWire since May 8, 2005. Is that correct?
A Yes.
Q What I would like to do is just briefly, if you could walk me through Exhibit 279 and just for each block just talk at a very high, general

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level so we understand, what each block is and then after that I would like to go through the plant and try to talk about each block as we go through, but before we do that, I just want to mark these on the record.
We will mark DePuy Mitek Exhibit 282 as the Pearsalls Limited US2 FiberWire M/C state scoured FiberWire sample that was produced to us today.
(Depuy Mitek Exhibit 282 marked for identification)
DePuy Mitek Exhibit 283 is the Pearsalls Limited US2 FiberWire M/C state before scoured that was produced to us today.
(Depuy Mitek Exhibit 283 marked for identification)
DePuy Mitek Exhibit 284 is the Pearsalls Limited US2 FiberWire, M/C state scoured/dyed sample that was produced to us today.
(DePuy Mitek Exhibit 284 marked for identification)
DePuy Mitek Exhibit 285 is the Pearsalls Limited US2 FiberWire M/C state dye/coated sample that was produced to us today.
(DePuy Mitek Exhibit 285 marked for identification)
Would you just identify these for the record, if you would? Do you recognize Exhibit 282 as a Pearsalls Limited US2 FiberWire M/C state

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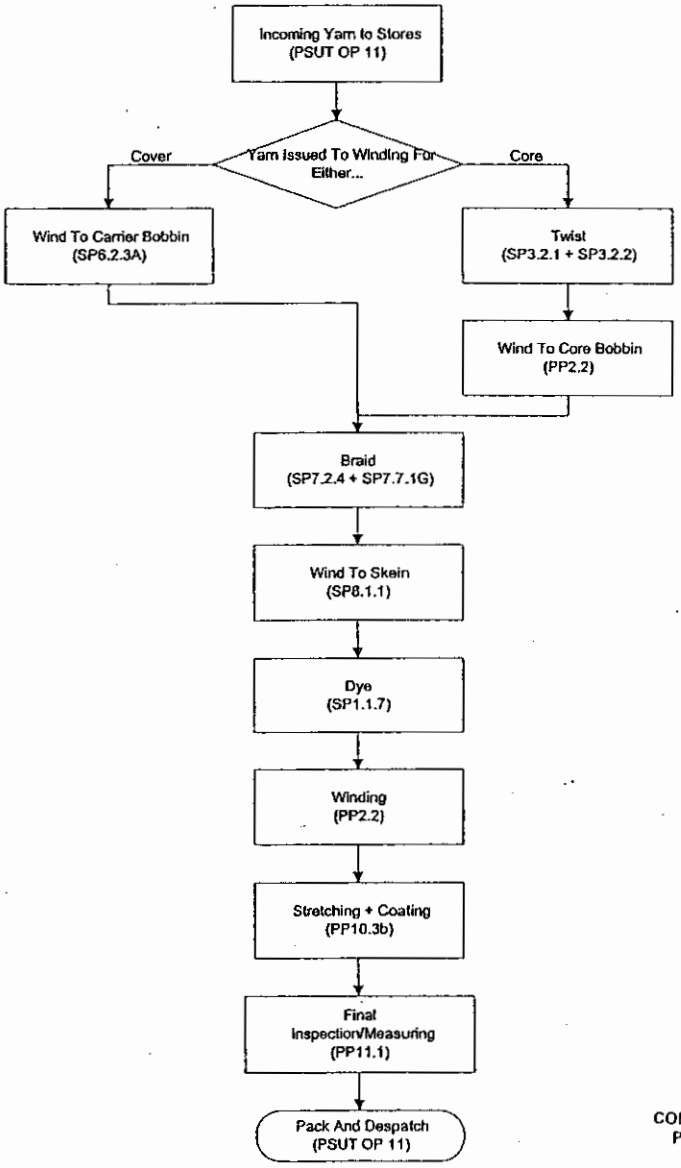
scoured sample that was produced to us?
A Yes.
Q Do you recognize DePuy Mitek Exhibit 283 as the Pearsalls Limited US2 FiberWire M/C state before scoured sample that was produced to us?
A Yes.
Q Do you recognize DePuy Mitek Exhibit 284 as the Pearsalls Limited US2 FiberWire M/C state scoured/dyed sample that was produced to us today?
A Yes.
Q Do you recognize the DePuy Mitek Exhibit 285 as the Pearsalls Limited US2 FiberWire M/C state dyed/coated sample that was produced to us today?
A Yes.
Q Let's just walk through the Exhibit 279 flowchart, if you would, and just tell us, beginning with the, "Incoming yarn to stores", block, what does that represent?
A That represents the yarn which has been brought into the factory.
Q For example, for flowchart -- for FiberWire that would represent the polyester and ultra high molecular weight polyethylene and the nylon?
A PET.

Pearsalls Sutures

Fibrewire Process Flowchart



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ARM 002554

QSM4.8-27 Page: 1 of 1 Issue: 2 Date: 29/06/01 Authorised:

EXHIBIT 20

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

JOINT PROPOSED STIPULATED FACTS

Stipulated Fact #1

Arthrex, Inc. received actual notice of U.S. Patent No. 5,134,446 on December 1, 2003 (J. Schmeiding 1/5/06 Dep. at 64:12-15).

Stipulated Fact #2

FiberWire and TigerWire are surgical sutures (FiberWire IFU)(Undisputed Mitek Fact #11; Arthrex Response to Mitek Request to Admit No. 3).

Stipulated Fact #3

RK Manufacturing has sold sterilized FiberWire and TigerWire to Arthrex, Inc. within the United States (Grieff Dep. at 37:23-38:8).

Stipulated Fact #4

Arthrex, Inc. sells FiberWire and TigerWire in the United States (ARM 3355)(Undisputed Mitek Fact #51).

Stipulated Fact #5

Pearsalls manufactures the braided products that are further processed and ultimately sold as FiberWire and TigerWire sutures (Grieff Dep. at 12:2-11; 12:18-23; 16:24-17:3; 17:9-12).

Stipulated Fact #6

Pearsalls has imported into the United States unsterilized braided products that are further processed and ultimately sold as FiberWire and TigerWire sutures (Grieff Dep. at 20:10-22).

Stipulated Fact #7

Pearsalls has sold unsterilized braided products to R.K. Manufacturing which are further processed and ultimately sold as FiberWire and TigerWire sutures and suture products (Grieff Dep. at 20:10-22).

Stipulated Fact #8

Arthrex, Inc. sells FiberWire and TigerWire sutures attached to a needle (DMI Ex. 5 at ARM 001469).

Stipulated Fact #9

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 101)(Undisputed Mitek Fact #26).

Stipulated Fact #10

Arthrex's sells the following FiberWire and TigerWire suture product codes within the United States: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (ARM 3355).

Stipulated Fact #11

FiberWire sutures and TigerWire sutures sold by Arthrex are sterilized (Arthrex Response to Mitek's Request to Admit No. 3)(DMI Ex. 3 at 13-1).

Stipulated Fact #12

The cover in FiberWire suture is constructed of ultra high molecular weight polyethylene (UHMWPE) and polyethylene terephthalate (PET) (Arthrex Response to Mitek's Request to Admit No. 9).

Stipulated Fact #13

FiberWire includes a heterogeneous braid composed of a first and second set of continuous and discrete yarns (Mukherjee Dep. at 362:1-4)(Undisputed Mitek Fact #13).

Stipulated Fact #14

FiberWire includes a set of PET yarns made up of a plurality of PET filaments (Dreyfuss Dep. at 64:14-17).

Stipulated Fact #15

Each FiberWire suture product has a set of yarns made of PET (*id.*)(Undisputed Mitek Fact #49).

Stipulated Fact #16

Each yarn of PET included in FiberWire is composed of a plurality of filaments (Mukherjee Dep. at 363:7-16)(Undisputed Mitek Fact #46).

Stipulated Fact #17

FiberWire includes a set of UHMW PE yarns made up of a plurality of UHMW PE filaments (Dreyfuss Dep. at 50:21-51:1)

Stipulated Fact #18

In FiberWire, at least one yarn of ultra high molecular weight PE is in direct intertwining contact with a PET yarn (Dreyfuss Dep. at 50:21-51:1).

Stipulated Fact #19

FiberWire includes a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction (Mukherjee Dep. at 362:5-8)(Undisputed Mitek Fact #13).

Stipulated Fact #20

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id*. at 362:1-4)(Undisputed Mitek Fact #15).

Stipulated Fact #21

The ultra high molecular weight polyethylene yarns in FiberWire and Tiger Wire are continuous and discrete (*id.*)

Stipulated Fact #22

The PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET (Dreyfuss 9/16/05 Dep. at 64:14-17)(Undisputed Mitek Fact #17).

Stipulated Fact #23

No. 2 FiberWire suture, No. 5 FiberWire, No. 0 FiberWire suture, the No. 2-0 FiberWire suture, and the 3-0 FiberWire suture are braided using the same process (Dreyfuss 9/16/05 Dep. at 38:20-24)(Undisputed Mitek Fact #23).

Stipulated Fact #24

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (DMI Ex. 318)(Undisputed Mitek Fact #47).

Stipulated Fact #25

Notwithstanding the color of the yarns, TigerWire's yarns are identical to FiberWire's yarn with the exception that one PET yarn is replaced by one nylon yarn (DMI Ex. 318)(Undisputed Mitek Fact #9).

Stipulated Fact 26

The addition of nylon to TigerWire does not materially affect the basic and novel characteristics of the invention.

Stipulated Fact #27

TigerWire is braided in the same way as FiberWire (Dreyfuss 9/16/05 at 31:24–32:2)(Undisputed Mitek Fact #10).

Stipulated Fact #28

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Brookstein Op. Expert Rpt. at ¶49; DMI Ex. 318)(Undisputed Mitek Fact #50).

Stipulated Fact #29

FiberWire size 4-0 does not have a core (*id*. at 55:21-23)(Undisputed Mitek Fact #25).

Stipulated Fact #30

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id*. at 104:17-105:9)(Undisputed Mitek Fact #24).

Stipulated Fact #31

Tevdek is a 100% braided polyester suture (Sluss Dep. at 35:17-22; *See* Grafton Dep. at 36:17-18).

Stipulated Fact #32

Mr. Grafton's idea was to add the PET and to improve the knot security of the suture (Undisputed Mitek Fact #30)(*id*. at 53:24-54:5).

Stipulated Fact #33

The FiberWire prototype suture that included PET braided with ultra-high molecular weight polyethylene had good knot security (*id*. at 54:24-55:1)(Undisputed Mitek Fact #31).

Stipulated Fact #34

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 284, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes that are before the dying process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 36:1-4; 36:19-12; DMI Ex. 279).

Stipulated Fact #35

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 285, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process (Hallett 1/11/2006 Dep. at 37:10-13; DMI Ex. 279).

Stipulated Fact 36

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 286, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process. It is the same as US 2 commercial FiberWire(Hallett 1/11/2006 Dep. at 38:17-39:6; 39:12-18;40:2-9, 12-17; 41:5-11; DMI Ex. 279).

Stipulated Fact #37

DePuy Mitek Deposition Exhibit 317 sets forth specification acceptance criteria for FiberWire (Hallett 1/12/2006 Dep. at 241:15-18).

Stipulated Fact #38

Pearsalls' batch records were generated in the normal course of Pearsalls' business (Hallett 1/12/2006 Dep. at 269:5-11).

Stipulated Fact #39

Plaintiff DePuy Mitek, Inc. ("DePuy Mitek") is a corporation organized under the laws of the State of Massachusetts and maintains its principal place of business at 325 Paramount Drive, Raynham, Massachusetts 02767.

Stipulated Fact#40

Defendant Arthrex, Inc. ("Arthrex") is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 1370 Creekside Boulevard, Naples, Florida 34108.

Stipulated Fact #41

Defendant Pearsalls, Ltd. ("Pearsalls") is a corporation organized under the laws of the United Kingdom and maintains its principal place of business at Tancred Street, Taunton, Somerset, England.

Stipulated Fact #42

Ethicon, Inc. ("Ethicon") is a corporation organized under the laws of the State of New Jersey and maintains it principal place of business at U.S. Route 22 West, P.O. Box 151, Sommerville, New Jersey 08876-0151.

Stipulated Fact #43

Arthrex sells FiberWire suture in the United States, as stand-alone suture, and also attached to needles or suture anchors.

Stipulated Fact #44

Arthrex's FiberWire suture contains a braid of ultra high molecular weight polyethylene (UHMWPE) and PET.

Stipulated Fact #45

Arthrex's FiberWire suture includes a coating of NuSil Med 2174.

Stipulated Fact #46

Arthrex's TigerWire suture contains a braid of ultra high molecular weight polyethylene (UHMWPE) , PET, and one nylon yarn.

Stipulated Fact #47

Arthrex's TigerWire suture includes a coating of NuSil Med 2174.

Stipulated Fact #48

Arthrex's FiberWire sutures are tipped.

Stipulated Fact #49

Arthrex's TigerWire sutures are tipped.

Stipulated Fact #50

DePuy Mitek and Ethicon, Inc. are affiliated with Johnson & Johnson.

Stipulated Fact #51:

Before Dr. Gitis conducted the tests described in his report dated March 23, 2006, Dr. Gitis sent, via Fedex, two envelopes containing U.S. No. 2 FiberWire suture to Sterile Systems, in Grand Rapids, Michigan. One of the envelopes Dr. Gitis sent to Sterile Systems contained a plastic bag of suture and was labeled "coated." The other envelope Dr. Gitis sent to Sterile

Systems contained a plastic bag of suture and was labeled “uncoated.” The sutures were sterilized in the envelopes at Sterile Systems. The two envelopes of suture were then returned to Dr. Gitis at CETR.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S RESPONSE TO DEPUY MITEK'S DRAFT PROPOSED STIPULATED FACTS OF JUNE 29, 2007

Stipulated Fact #1

DePuy Mitek owns U.S. Patent No. 5,314,446 and has owned it since August, 2004 (DMI000338-340).

OBJECT -- ownership of '446 patent being contested

Stipulated Fact #2

Ethicon, Inc. owned U.S. Patent No. 5,134,446 from May 24, 1994 until August, 2004 (446 Patent; DMI000338-340).

OBJECT -- ownership of '446 patent being contested

Stipulated Fact #3

Arthrex, Inc. received actual notice of U.S. Patent No. 5,134,446 on December 1, 2003 (J. Schmeiding 1/5/06 Dep. at 64:12-15).

OBJECT – irrelevant – goes to willfulness

Stipulated Fact #4

FiberWire and TigerWire are surgical sutures (FiberWire IFU)(Undisputed Mitek Fact #11; Arthrex Response to Mitek Request to Admit No. 3).

AGREE

Stipulated Fact #5

Pearsalls manufactures FiberWire and TigerWire (Grieff Dep. at 12:2-11; 12:18-23; 16:24-17:3; 17:9-12).

OBJECT – Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #6

FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 279 (Hallett 1/11/2006 Dep. at 12:21-13:9; 13:15-19).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #7

FiberWire and TigerWire have been manufactured according to the procedures set forth in DePuy Mitek Ex. 281 (Hallett 1/11/2006 Dep. at 14:8-16; 19:10-13).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #8

Pearsalls has imported unsterilized FiberWire and TigerWire into the United States (Grieff Dep. at 20:10-22).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #9

Pearsalls has sold unsterilized FiberWire and TigerWire in the United States to R.K. Manufacturing (Grieff Dep. at 20:10-22).

OBJECT -- Pearsalls manufactures braids used in FiberWire and TigerWire

Stipulated Fact #10

RK Manufacturing does nothing to alter the construction of the braid it receives from Pearsalls and sells to Arthrex (Ponton Dep. at 74:16-21).

OBJECT – "alter the construction" is undefined, confusing and misleading

Stipulated Fact #11

RK Manufacturing has sold sterilized FiberWire and TigerWire to Arthrex, Inc. within the United States (Grieff Dep. at 37:23-38:8).

AGREE

Stipulated Fact #12

Arthrex, Inc. sells FiberWire and TigerWire in the United States (ARM 3355)(Undisputed Mitek Fact #51).

AGREE

Stipulated Fact #13

For all FiberWire and TigerWire products sold outside of the United States, Arthrex, Inc. supplies those products from the United States. (Grieff Dep. at 70:16-24; 71:1-5, 6; 13-17).

OBJECT – irrelevant

Stipulated Fact #14

Arthrex, Inc. sells FiberWire and TigerWire sutures attached to a needle (DMI Ex. 5 at ARM 001469).

AGREE

Stipulated Fact #15

Arthrex's FiberWire and TigerWire suture products include at least the products having the following Arthrex catalog product codes: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-

1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (DMI Ex. 101)(Undisputed Mitek Fact #26).

AGREE

Stipulated Fact #16

Arthrex's sells the following FiberWire and TigerWire suture product codes within the United States: AR-7200, AR-7201, AR-7202, AR-7203, AR-7204, AR-7205, AR-7205T, AR-7207, AR-7209, AR-7209SN, AR-7209T, AR-7210, AR-7211, AR-7219, AR-7220, AR-7221, AR-7222, AR-7223, AR-7225, AR-7227-01, AR-7227-02, AR-7228, AR-7229-12, AR-7229-20, AR-7230-01, AR-7230-02, AR-7232-01, AR-7232-02, AR-7232-03, AR-7237, AR-7250, AR-7251, AR-1320BNF, AR-1322BNF, AR-1322-75SF, AR-1322-752SNF, AR-1915SNF, AR-1920SNF, AR-1322SX, AR-1322SXF, AR-1324B, AR-1324BF, AR-1324BF-2, AR-1324BNF, AR-1324HF, AR-1324SF,AR-1934BF, AR-1934BF-2,AR-1934BFT, AR-1934BFX, AR-1934BNF, AR-1934BLF, AR-1915SF, AR-1920BF, AR-1920BF-37, AR-1920BFT, AR-1920BN, AR-1920BNF, AR-1920BNP, AR-1920BT, AR-1920SF, AR-1920SFT, AR-1925BF, AR-1925BFSP, AR-1925BNF, AR-1925BNP, AR-1925SF,AR1927-BF, AR-1927BNF, AR-1928SF, AR-1928SF-2, AR-1928SNF, AR-1928SNF-2, AR-2225S, and AR-2226S (ARM 3355).

AGREE

Stipulated Fact #17

FiberWire sutures and TigerWire sutures sold by Arthrex are sterilized (Arthrex Response to Mitek's Request to Admit No. 3)(DMI Ex. 3 at 13-1).

AGREE

Stipulated Fact #18

The cover in FiberWire suture is constructed of ultra high molecular weight polyethylene (UHMWPE) and polyethylene terephthalate (PET) (Arthrex Response to Mitek's Request to Admit No. 9).

AGREE

Stipulated Fact #19

FiberWire is a heterogeneous braid composed of a first and second set of continuous and discrete yarns (Mukherjee Dep. at 362:1-4)(Undisputed Mitek Fact #13).

OBJECT – incorrect – FiberWire *includes* a heterogeneous braid composed of a first and second set of continuous and discrete yarns

Stipulated Fact #20

FiberWire includes a set of PET yarns made up of a plurality of PET filaments (Dreyfuss Dep. at 64:14-17).

AGREE

Stipulated Fact #21

Each FiberWire suture product has PET as a second set of yarns (*id*.)(Undisputed Mitek Fact #49).

OBJECT – confusing attempt to reference claim language – no context

Stipulated Fact #22

FiberWire has each yarn from the second set composed of a plurality of filaments of a second fiber-forming material of PET (Mukherjee Dep. at 363:7-16)(Undisputed Mitek Fact #46).

OBJECT – confusing attempt to reference claim language – no context

Stipulated Fact #23

FiberWire includes a set of UHMW PE yarns made up of a plurality of UHMW PE filaments (Dreyfuss Dep. at 50:21-51:1)

AGREE

Stipulated Fact #24

In FiberWire, at least one yarn of ultra high molecular weight PE is in direct intertwining contact with a PET yarn (Dreyfuss Dep. at 50:21-51:1).

AGREE

Stipulated Fact #25

FiberWire is a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction (Mukherjee Dep. at 362:5-8)(Undisputed Mitek Fact #13).

OBJECT – incorrect – FiberWire *includes* a heterogeneous sheath braid composed of discrete yarns in a sterilized braided construction

Stipulated Fact #26

The polyethylene terephthalate yarns in FiberWire and TigerWire are continuous and discrete (*id*. at 362:1-4)(Undisputed Mitek Fact #15).

AGREE

Stipulated Fact #27

The ultra high molecular weight polyethylene yarns in FiberWire and Tiger Wire are continuous and discrete (*id.*)

AGREE

Stipulated Fact #28

The PET used in Arthrex's FiberWire sutures is in the form of yarn, and that PET yarn is made up of several twisted monofilaments of PET (Dreyfuss 9/16/05 Dep. at 64:14-17)(Undisputed Mitek Fact #17).

AGREE

Stipulated Fact #29

No. 2 FiberWire suture, No. 5 FiberWire, No. 0 FiberWire suture, the No. 2-0 FiberWire suture, and the 3-0 FiberWire suture are braided using the same process (Dreyfuss 9/16/05 Dep. at 38:20-24)(Undisputed Mitek Fact #23).

AGREE

Stipulated Fact #30

Arthrex's FiberWire sutures have a core except for 4-0 FiberWire (DMI Ex. 318)(Undisputed Mitek Fact #47).

AGREE

Stipulated Fact #31

The purpose of the nylon marking strand in Arthrex's TigerWire product is visual identification (Dreyfuss 12/7/05 Dep. at 74:21-23)(Undisputed Mitek Fact #39).

OBJECT – irrelevant – Defendants not making distinction between FiberWire and TigerWire for purposes of this trial

Stipulated Fact #32

Notwithstanding the color of the yarns, TigerWire's yarns are identical to FiberWire's yarn with the exception that one PET yarn is replaced by one nylon yarn (DMI Ex. 318)(Undisputed Mitek Fact #9).

AGREE

Stipulated Fact #33

TigerWire is braided in the same way as FiberWire (Dreyfuss 9/16/05 at 31:24–32:2)(Undisputed Mitek Fact #10).

AGREE

Stipulated Fact #34

Every FiberWire and TigerWire construction has a ratio of the cross-sectional area of ultra high molecular weight PE in the sheath and core to the total cross sectional area of all the yarns in the surgical suture that ranges from 20 to 80 percent (Brookstein Op. Expert Rpt. at ¶49; DMI Ex. 318)(Undisputed Mitek Fact #50).

AGREE

Stipulated Fact #35

FiberWire size 4-0 does not have a core (*id*. at 55:21-23)(Undisputed Mitek Fact #25).

AGREE

Stipulated Fact #36

The FiberWire size 4-0 suture has the same sheath configuration as the other size FiberWire sutures (*id*. at 104:17-105:9)(Undisputed Mitek Fact #24).

AGREE

Stipulated Fact #37

Ultra-high molecular weight polyethylene is a lubricious material (*id*. at 52:24-53:1)(Undisputed Mitek Fact #29).

OBJECT – no context given

Stipulated Fact #38

Tevdek is a 100% braided polyester suture (Sluss Dep. at 35:17-22; *See* Grafton Dep. at 36:17-18).

AGREE

Stipulated Fact #39

The initial FiberWire prototype was 100 percent ultra-high molecular weight polyethylene (Grafton Dep. at 51:15-17)(Undisputed Mitek Fact #27).

OBJECT – "initial FiberWire prototype" undefined and also irrelevant

Stipulated Fact #40

When developing FiberWire, Arthrex considered a 100% ultra high molecular weight PE braid before it considered braiding ultra high molecular weight PE with PET (Grafton Dep. at 51:15-17)(Undisputed Mitek Fact #139).

OBJECT – irrelevant

Stipulated Fact #41

The knot slippage of the 100% ultra-high molecular weight polyethylene suture was poor because of the lubricity of polyethylene (*id*. at 53:2-5)(Undisputed Mitek Fact #29).

OBJECT -- irrelevant

Stipulated Fact #42

The knot security of the initial FiberWire prototype made from 100 percent ultra-high molecular weight polyethylene was poor (*id*. at 51:4-7; 53:20-23)(Undisputed Mitek Fact #30).

OBJECT -- irrelevant

Stipulated Fact #43

Mr. Grafton's idea was to add the PET and to improve the knot security of the suture (Undisputed Mitek Fact #30)(*id*. at 53:24-54:5).

AGREE

Stipulated Fact #44

The FiberWire prototype suture that included PET braided with ultra-high molecular weight polyethylene had good knot security (*id*. at 54:24-55:1)(Undisputed Mitek Fact #31).

AGREE

Stipulated Fact #45

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 282, underwent all FiberWire manufacturing processes prior to the wind to skein process and the scouring process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 33:3-34:7; 36:16-18).

OBJECT – irrelevant

Stipulated Fact #46

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 283, underwent the FiberWire braiding process and all FiberWire manufacturing processes that are before the braiding process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 35:10-13; DMI Ex. 279).

OBJECT -- irrelevant

Stipulated Fact #47

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 284, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes that are before the dying process, but no other FiberWire manufacturing processes (Hallett 1/11/2006 Dep. at 36:1-4; 36:19-12; DMI Ex. 279).

AGREE

Stipulated Fact #48

The FiberWire sample, denoted as DePuy Mitek Deposition Ex. 285, underwent the FiberWire scouring and dying processes and all FiberWire manufacturing processes before the "final inspection/measuring" process (Hallett 1/11/2006 Dep. at 37:10-13; DMI Ex. 279).

AGREE

Stipulated Fact #49

The FiberWire sample, denoted as DePuy Mitek Deposition Exhibit 342, under went all of the manufacturing process in DePuy Mitek Exhibit 279 before the stretching and coating

processes, and once coated, stretched, and heated a single time (Hallett 1/12/2006 Dep. at 349:7-13; 350:1-5).

OBJECT – irrelevant and confusing

Stipulated Fact #50

Pearsalls' "dye stage" testing occurs after the dying and scouring process but before the winding, stretching and coating, and final inspection/measuring processes (Hallett 1/11/2006 at 47:24-48:3; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #51

Pearsalls' "intermediate" testing occurs after the stretching and coating processes in Mitek deposition Ex. 279 but before the final inspection/measuring processes (Hallett 1/11/2006 Dep. at 49:14-16; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #52

Pearsalls' final stage measuring test occurs after the stretching and coating processes in Mitek deposition Ex. 279 and when Pearsalls' has completed manufacturing the product (Hallett 1/11/2006 Dep. at 53:18-25; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #53

There should not be any construction or manufacturing difference between FiberWire samples from the same batch that are tested at Pearsalls' intermediate and final tests (Hallett 1/11/2006 Dep. at 54:1-6; DMI Ex. 279).

OBJECT – irrelevant and confusing

Stipulated Fact #54

DePuy Mitek Deposition Exhibit 316 sets forth specification tolerances for FiberWire (Hallett 1/12/2006 at 237:9-11; 240:21-24).

OBJECT – irrelevant and incorrectly describes document

Stipulated Fact #55

DePuy Mitek Deposition Exhibit 317 sets forth specification acceptance criteria for FiberWire (Hallett 1/12/2006 Dep. at 241:15-18).

AGREE

Stipulated Fact #56

DePuy Mitek Deposition Exhibit 318 is a matrix for the developmental and commercial FiberWire and TigerWire products (Hallett 1/12/2006 Dep. at 245:21-25).

OBJECT – irrelevant and confusing

Stipulated Fact #57

Pearsalls' batch records were generated in the normal course of Pearsalls' business (Hallett 1/12/2006 Dep. at 269:5-11).

AGREE

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

----------x

DEPUY MITEK, INC, a Massachusetts Corporation,

Plaintiff,

-against- Civil Action No. 04-12457PBS

ARTHREX INC., a Delaware Corporation and Pearsalls Limited, a Private Limited Company of the United Kingdom,

Defendants.

----------x

18 Old Ridgebury Road
Danbury, Connecticut

December 14, 2005
9:00 a.m.

VIDEOTAPED DEPOSITION of RICHARD PONTON

taken before Cheryll Kerr, LSR, a Licensed Shorthand Reporter within and for the State of Connecticut.

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previous address, and I don't have that address.
I believe it was Six Finance Drive, but I am not -- I could not confirm that accurately.
Q. Okay. Does RK Manufacturing ever change or alter the braid construction of the braided suture that it receives from Pearsalls that RK Manufacturing manufactures for Arthrex as FiberWire sutures or suture products?
MR. TAMBURO: Objection, asked and answered.
BY MR. FALKE:
Q. You can answer.
A. Okay.
Q. Do you want me to repeat it?
A. Yes, please.
Q. Does RK Manufacturing ever change the braid design and construction of the bulk suture that it receives from Pearsalls and that RK Manufacturing makes into Arthrex FiberWire sutures or suture products?
A. No.
Q. Exhibit 182 -- do you know who created that?
A. I believe it was done by Mary-Ellen.
Q. Okay, and do you believe Exhibit 182 to

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accurately reflect all the steps that RK Manufacturing does with respect to Arthrex FiberWire sutures and suture products?
A. Yes.
MR. FALKE: Okay. I have no further questions at this time.
MR. TAMBURO: Okay.
THE VIDEOGRAPHER: Going off the record. The time is 11:04.
(Time noted: 11:04 a.m.)

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STATE OF CONNECTICUT

I, CHERYLL KERR, A Licensed Shorthand Reporter duly commissioned and qualified in and for the State of Connecticut, do hereby certify that pursuant to notice there came before me on the 14th day of December, 2005, the following person to wit: Richard Ponton, who was duly sworn to testify to the truth and nothing but the truth; that he was thereupon carefully examined upon his oath and his examination reduced to writing under my supervision; that this deposition is a true record of the testimony given by the witness.

I further certify that I am neither attorney nor counsel for nor related to nor employed by any of the parties to the action in which this deposition is taken and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto, or financially interested in this action.

IN WITNESS THEREOF, I have hereunto set my hand this 14th day of December, 2005.

Cheryll Kerr, LSR

_____

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JURAT

I, Richard Ponton, do hereby certify that the foregoing testimony given by me on December 14, 2005 is true and accurate, including any corrections noted on the corrections page, to the best of my knowledge and belief.

_____
Richard Ponton

Subscribed to and sworn before me on this _____ day of _____ 2005.

My Commission Expires: _____.

EXHIBIT 21

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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deposition of:

BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
11th January 2006

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except for the steam setting process that is caught up in the cover?
A Yes.
Q Did the FiberWire, Exhibit 282, undergo any process after the wind to skein process, just the scour one?
A That is just scoured.
Q Just scoured. Okay. I will show you another copy of Exhibit 279 where we just wrote, "279", at the top. Could you mark on Exhibit 279 where Exhibit 282 was taken, just so that we can have it for the record?
A Where it was taken from?
Q Right. During the process. Would you just label that DePuy Mitek Exhibit 282? Just Exhibit, "EX 282", and your own arrow to that, if you would. So, where you have drawn -- written -- "EX 282", on Exhibit 279, that represents where the FiberWire Exhibit 282 was taken?
A Hmm hmm.
Q Now I will show you DePuy Mitek Exhibit 283. This is the one labeled, "Pearsalls Limited US2 FiberWire M/C state before scoured".
A Yes.
Q Can you label on Exhibit 279 where that

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was taken? (Pause)
So, the Exhibit 283 sample you marked as being taken after the braiding process on Exhibit 279.
A Correct.
Q So, the FiberWire in Exhibit 283 underwent all the processes before the braiding process that are in Exhibit 279?
A Repeat the question?
Q Sure. The FiberWire that is in the sample, Exhibit 283, underwent all the processes that are before the braiding process in Exhibit 279; correct?
A Yes.
Q I would like to show you Exhibit 284. It is the Pearsalls Limited US2 FiberWire 10/C state scoured/dyed sample. Can you label where the Exhibit 284 sample was taken? (Pause)
So, where you have written, "EX 284", is where the DePuy Mitek Exhibit 284 sample was taken; correct?
A Yes.
Q You have labeled the Exhibit 284 sample as being taken before the Exhibit 282 sample. Is that right?
A That's correct.

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Q Is it -- the Exhibit 284 sample underwent the dyeing process and all the processes that are before the dyeing process in Exhibit 279?
A Correct.
Q The Exhibit 282 -- 284 -- was the Exhibit 284 sample scoured?
A Yes. Scoured and dyed.
Q The difference between exhibit --
A That was taken out before it was dyed.
Q I am sorry, say again?
A It was taken out of the machine before it gets dyed. It just goes through a scouring process.
Q Is there a scouring process before and after the dyeing process or just before?
A It is before.
Q Exhibit 282 was taken after the scouring but before the dyeing?
A Yes.
Q Exhibit 284 was taken after the scouring and after the dyeing?
A Yes.
Q You have labeled them on the chart as 284 coming first, but that is not really right. 284 comes after --
A Yes. It is the other way around,

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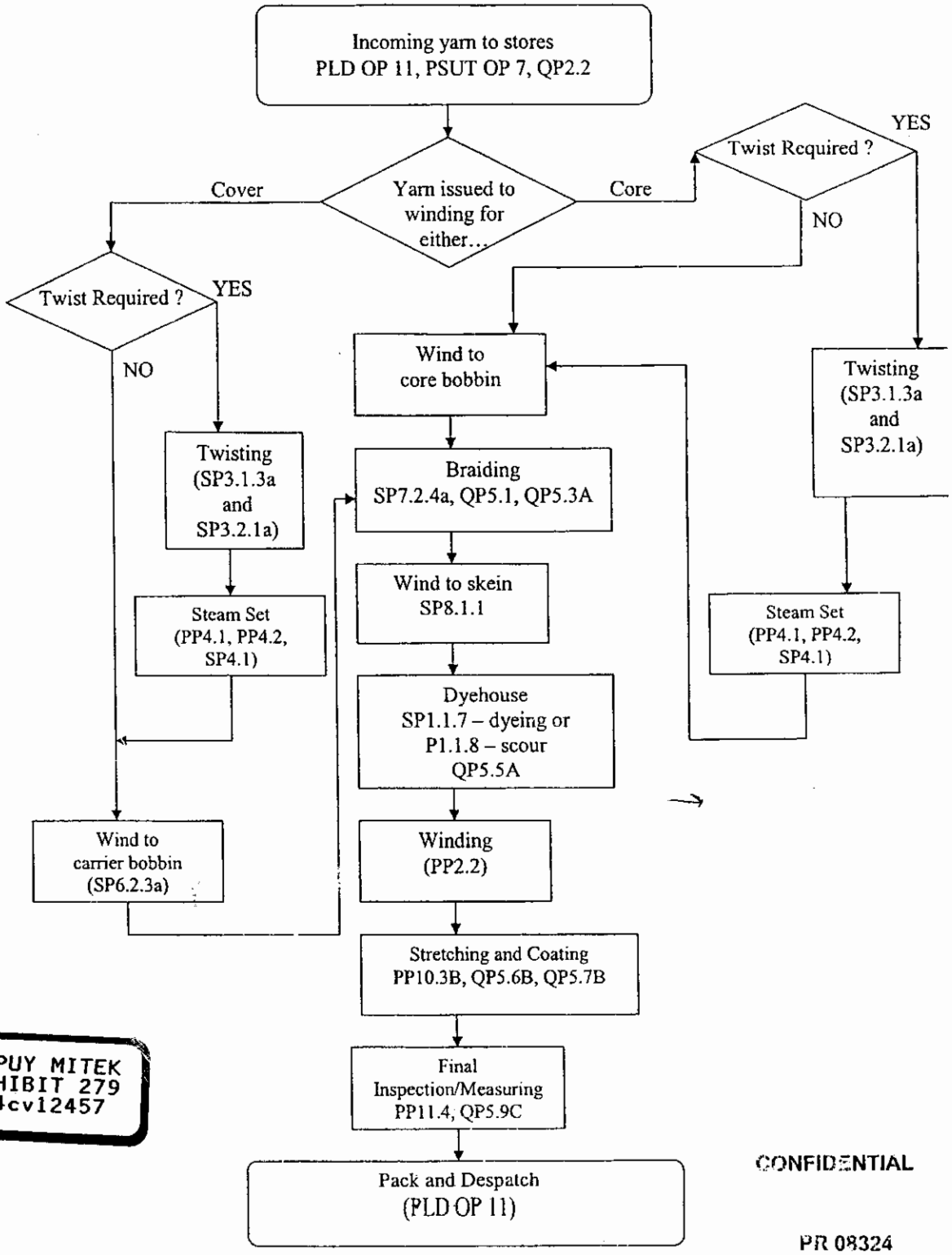
actually, as that is written down.
Q DePuy Mitek Exhibit 285 is entitled, "US2 FiberWire, M/C state dyed/coated"?
A Hmm hmm.
Q Can you label where Exhibit 285 was taken? (Pause)
Now, you have labeled Exhibit 285 as the stretching coating block; correct?
A Correct.
Q Exhibit 285 FiberWire was -- underwent all the processes before the final inspection measuring process. Is that correct?
A Correct.
Q So, Exhibit 285 was stretched and coated; correct?
A Correct.
Q So, the differences between Exhibit 284 and 285 is Exhibit 285 was wound and then stretched and then coated; correct?
A Correct.
Q Any other differences between Exhibit 284 and 285?
A No.
Q Exhibits 282, 283, 284 and 285, when were they taken?

Pearsalls Sutures

Fibrewire/Tigerwire Flowchart



DEPUY MITEK
EXHIBIT 279
04cv12457

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PR 08324

EXHIBIT 22

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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UNITED KINGDOM

on
11th January 2006

together for further processing.
Q And then what happens in the, "Dyehouse", block?
A The dyehouse? The skeins are then loaded onto what we call a, "Dye crown", and submerged into a dye vessel where the dyeing takes place, which is done under a programme in a high-pressure dyeing machine.
Q That is for dyeing the FiberWire blue?
A Yes.
Q Any other dyeing which takes place during -- dye colour that takes place during that process for FiberWire or TigerWire?
A No.
Q Did TigerWire, with the black strand -- are you familiar with that?
A Yes.
Q The material that is blacked is nylon, right?
A Yes.
Q The nylon comes back black so you don't have to dye it?
A No.
Q You do dye it?
A Yes.

Q Is that reflected on the flowchart?
A No.
Q Does that happen before --
A That happens before they get to there.
Q Before the twist?
A Yes. The nylon is not twisted?
Q It is not?
A No. Not at that stage.
Q No? Is the nylon ever twisted?
A Yes.
Q It is?
A Hmm hmm.
Q Is the nylon manufactured according to the cover section of the -- of the flowchart?
A Can you repeat the question?
Q Sure. The cover section of the flowchart, does that reflect the manufacturing processes for the nylon, other than the steam set?
A No. It is not shown on there.
Q So, when it says, "Cover can go, here, that is really referring to the polyester and ultra high molecular weight polyethylene?
A Yes.
Q Is there a separate flowchart for nylon?
A I am not sure.

Q After -- you have mentioned the dyeing. What is the scouring process that is referred to?
A It is a cleaning process.
Q Then there is a winding process after the dyeing?
A They have got a -- from the skein it goes back to a bobbin so we can further process it.
Q It is wound. Okay. And then after that, after -- I am sorry, when it is wound, is it wound on a bobbin?
A From a skein, yes.
Q After it is wound, then it is stretched and coated?
A Yes. Hmm hmm. It is pad-stretched.
Q Is it hot-stretched before it is coated or after?
A At the same time.
Q At the same time. After its coating it goes to the final inspection and measuring process?
A Correct.
Q What does the final inspection measuring entail?
A It is wound to a finished bobbin where the operators are inspecting the product, and it is wound to certain lengths. After that, after the

final stretching and measuring it is packed and despatched.
Q DePuy Mitek Exhibit 282, the US2 FiberWire M/C state scoured sample, can you show me on the flowchart where that sample was taken during the manufacturing process?
A Here.
Q You are referring to Exhibit 279, the, "Dyehouse", block?
A Yes.
Q Now, it says dyeing or scouring there.
A Hmm hmm.
Q The Exhibit 282 sample is not dyed; correct?
A No. That is machine state.
Q Exhibit 282 is not dyed?
A Not dyed.
Q Has the FiberWire, Exhibit 282, been scoured?
A Yes.
Q So, the FiberWire, Exhibit 282, underwent the wind to skein process in the flowchart; right?
A Correct.
Q The FiberWire, Exhibit 282, underwent all the processes prior to the wind to skein process

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except for the steam setting process that is caught up in the cover?
A Yes.
Q Did the FiberWire, Exhibit 282, undergo any process after the wind to skein process, just the scour one?
A That is just scoured.
Q Just scoured. Okay. I will show you another copy of Exhibit 279 where we just wrote, "279", at the top. Could you mark on Exhibit 279 where Exhibit 282 was taken, just so that we can have it for the record?
A Where it was taken from?
Q Right. During the process. Would you just label that DePuy Mitek Exhibit 282? Just Exhibit, "EX 282", and your own arrow to that, if you would. So, where you have drawn -- written -- "EX 282", on Exhibit 279, that represents where the FiberWire Exhibit 282 was taken?
A Hmm hmm.
Q Now I will show you DePuy Mitek Exhibit 283. This is the one labeled, "Pearsalls Limited US2 FiberWire M/C state before scoured".
A Yes.
Q Can you label on Exhibit 279 where that

35

was taken? (Pause)
So, the Exhibit 283 sample you marked as being taken after the braiding process on Exhibit 279.
A Correct.
Q So, the FiberWire in Exhibit 283 underwent all the processes before the braiding process that are in Exhibit 279?
A Repeat the question?
Q Sure. The FiberWire that is in the sample, Exhibit 283, underwent all the processes that are before the braiding process in Exhibit 279; correct?
A Yes.
Q I would like to show you Exhibit 284. It is the Pearsalls Limited US2 FiberWire 10/C state scoured/dyed sample. Can you label where the Exhibit 284 sample was taken? (Pause)
So, where you have written, "EX 284", is where the DePuy Mitek Exhibit 284 sample was taken; correct?
A Yes.
Q You have labeled the Exhibit 284 sample as being taken before the Exhibit 282 sample. Is that right?
A That's correct.

36

Q Is it -- the Exhibit 284 sample underwent the dyeing process and all the processes that are before the dyeing process in Exhibit 279?
A Correct.
Q The Exhibit 282 -- 284 -- was the Exhibit 284 sample scoured?
A Yes. Scoured and dyed.
Q The difference between exhibit --
A That was taken out before it was dyed.
Q I am sorry, say again?
A It was taken out of the machine before it gets dyed. It just goes through a scouring process.
Q Is there a scouring process before and after the dyeing process or just before?
A It is before.
Q Exhibit 282 was taken after the scouring but before the dyeing?
A Yes.
Q Exhibit 284 was taken after the scouring and after the dyeing?
A Yes.
Q You have labeled them on the chart as 284 coming first, but that is not really right. 284 comes after --
A Yes. It is the other way around,

37

actually, as that is written down.
Q DePuy Mitek Exhibit 285 is entitled, "US2 FiberWire, M/C state dyed/coated"?
A Hmm hmm.
Q Can you label where Exhibit 285 was taken? (Pause)
Now, you have labeled Exhibit 285 as the stretching coating block; correct?
A Correct.
Q Exhibit 285 FiberWire was -- underwent all the processes before the final inspection measuring process. Is that correct?
A Correct.
Q So, Exhibit 285 was stretched and coated; correct?
A Correct.
Q So, the differences between Exhibit 284 and 285 is Exhibit 285 was wound and then stretched and then coated; correct?
A Correct.
Q Any other differences between Exhibit 284 and 285?
A No.
Q Exhibits 282, 283, 284 and 285, when were they taken?

EXHIBIT 23

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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BRIAN HALLETT

taken at:
The Castle Hotel
Castle Green
Taunton
Somerset
UNITED KINGDOM

on
12th January 2006

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A No.
Q How do you know at the measure stage it was -- in Exhibit 341 it was 16.482; right?
A So it is increased.
Q Check numbers. But how do you know -- it is increased. There is nothing done with the suture between the intermediate stage and the measure stage that would change the property of the suture; right?
A Hmm hmm.
Q Right?
A Yes.
Q Yes, I am correct?
A Yes, you are correct.
Q How do you know which one's right, the decreased one at the intermediate stage or the increased one at the end stage?
MR. TAMBURO: Calls for expert testimony and object to the form.
MR. BONELLA: Or were they all about the same?
A They all vary.
Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the

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other?
MR. TAMBURO: Objection, calls for expert testimony and speculation.
A Yes.
MR. BONELLA: That's correct?
A Yes.
MR. TAMBURO: Mike, this is the once-passed coating sample of US2 FiberWire. We don't have a Bates number but I will send you a Bates number by e-mail. It is a little capsule labeled, "Sample Pearsalls Limited blue FiberWire single coating 15 metres US2 batch number 28790".
MR. BONELLA: Okay. We will mark it as DP342 and ask Mr. Hallett if you can identify DePuy Mitek Exhibit 342, or take counsel's representation that it is number 2 blue FiberWire that has been run through the coating, stretching and drying process only one time. Is that correct?
(DePuy Mitek Exhibit 342 marked for identification)
MR. TAMBURO: That is my understanding yes.
MR. BONELLA: Can he testify to that? Does he know?

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MR. TAMBURO: I think he knows only what I know. He wasn't there watching it when it was done.
MR. BONELLA: All right. I will take your representation that it is what it is.
I will show you DePuy Mitek Exhibit 343. It is a three-page document test recorded summary and sign-off sheet from Arthrex. Sal, do you have any problems in me showing him Exhibit 343? It was disclosed to J&J as non-contentious.
MR. TAMBURO: No objection.
MR. BONELLA: Mr. Hallett, I am showing you Exhibit 343. I believe it has Brian Hallett's writing on the first page, I believe it is a document from Arthrex. Have you ever seen this document before?
(DePuy Mitek Exhibit 343 marked for identification)
A Yes.
Q You have?
A Hmm hmm.
Q When did you see it?
A Sometime last year.
Q And why did you see it?
A I think it was describing or showing the

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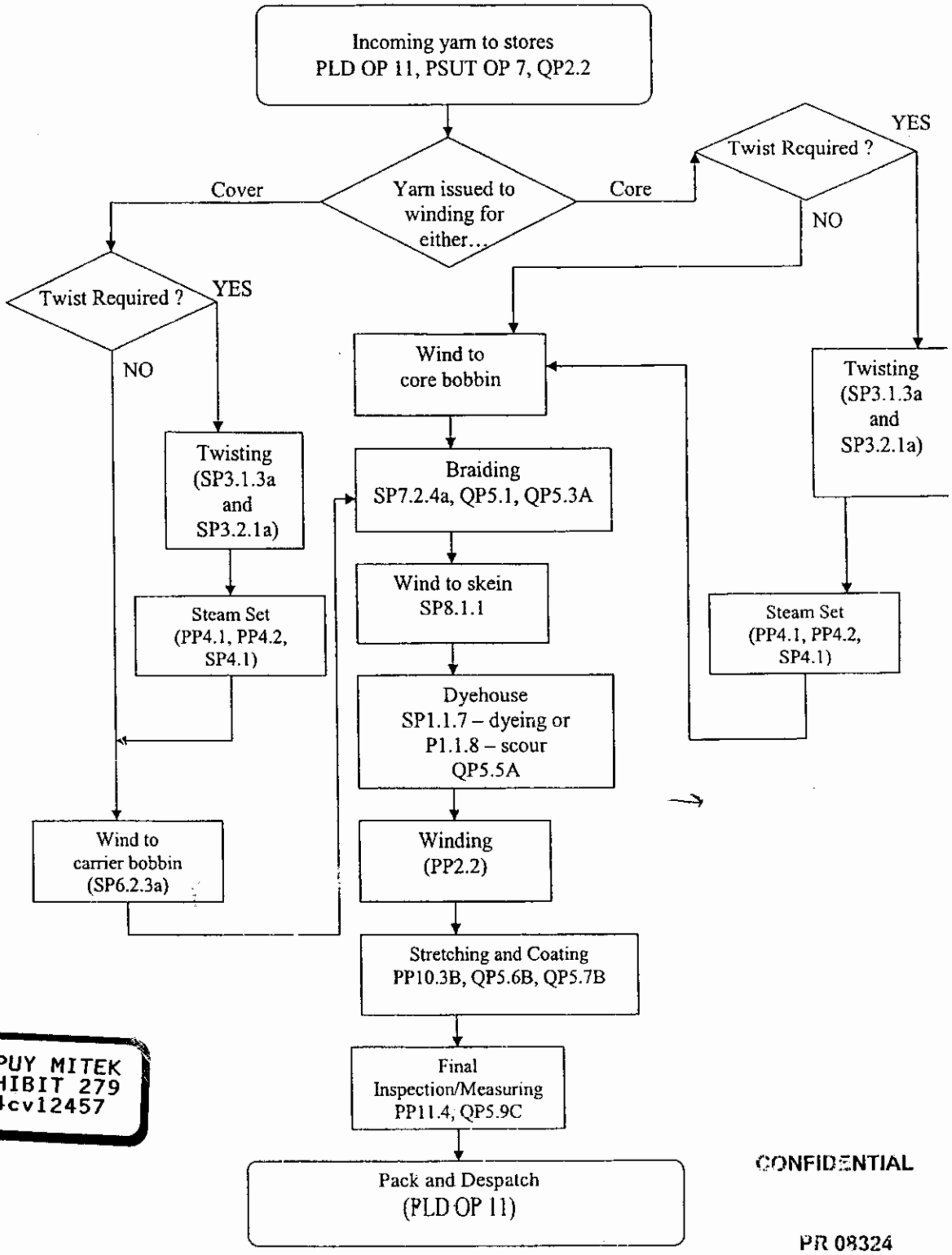
test procedure for doing a braid load on the loops.
Q On what?
A On the loop.
Q If you look at the top it says the description of the procedure on the first page is number 2 FiberWire 2174 coated and uncoated USIPG dyed, and the date is February 16, '04, and the type of test it says, knot tiedown, and it says:
"The test objective: To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture".
Do you see that?
A Hmm hmm.
Q The test method is described as:
"The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture

Pearsalls Sutures

Fibrewire/Tigerwire Flowchart



DEPUY MITEK
EXHIBIT 279
04cv12457

CONFIDENTIAL

PR 08324

EXHIBIT 24

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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taken at:
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Castle Green
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UNITED KINGDOM

on
12th January 2006

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Q In this document, it is 11.4a, but 11.4a does refer to FiberWire?
A That's correct.
Q Is 11.4a used in the manufacture of FiberWire?
A Yes.
Q Did 11.4a supersede 11.4?
A Yes.
Q You are able to obtain a FiberWire sample after one run of the coating stretching drying process?
A I am sorry, were we able to? Yes. I don't know, were we able to? I don't know. We didn't try at the time, since you asked.
MR. BONELLA: We would like to identify that before we go, if you can. If you want to produce it later and stipulate to its authenticity, that is fine.
MR. TAMBURO: Can we go off-the-record one second?
(9.49 am)
OFF THE RECORD
(10.00 am)
MR. BONELLA: Mr. Hallett, I will show you DePuy Mitek Exhibit 316. It is a two-page

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document entitled, "FiberWire Chart", dated November 11th, 2002. I am sorry. It is a one-page document. DePuy Mitek Exhibit 316 is a one-page document entitled, "FiberWire Chart", dated November 11th, 2002. Do you recognize Exhibit 316?
(DePuy Mitek Exhibit 316 marked for identification)
A Yes.
Q What is Exhibit 316?
A It is the specification tolerances for the FiberWire.
Q So, Pearsalls at one point in time in the manufacture of FiberWire meet -- at some point in time Pearsalls had to manufacture FiberWire to meet the specifications set forth in Exhibit 316?
A Yes.
Q Was Exhibit 316 later superseded?
A Yes.
Q Exhibit 316 spells out a knot pull, straight pull and a diameter specification; correct?
A That's correct.
Q Any other specifications that FiberWire had to meet other than a knot pull, straight pull and diameter?
A No.

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Q For each of the knot pull, straight pull and diameter, the specification was a minimum, a maximum, and a mean. Do you see that?
A Yes.
Q For each product listed in the chart, did the FiberWire products have to meet the minimum value, the maximum value and the mean value?
A The minimum.
Q Just the minimum?
A Hmm hmm.
Q The only acceptance criteria was the minimum knot pull, the minimum straight pull and the minimum diameter?
A That's correct.
Q The mean and the maximum were just guides?
A Guidelines, yes.
Q Was any FiberWire rejected for not meeting the maximum, or mean values?
MR. TAMBURO: Object to the form.
A No.
MR. BONELLA: Is the maximum diameter specification that has to be met -- and the reason I ask is because doesn't the USP sizes require a minimum and a maximum diameter?
A Yes.

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Q So yes, the maximum diameter is also a specification that FiberWire has to meet?
MR. TAMBURO: Objection, asked and answered.
A I don't know.
MR. BONELLA: You don't know?
A No.
Q Yesterday we looked at Exhibit 315 which was FiberWire acceptance criteria.
A That's correct.
Q Exhibit 315 talks about rejecting a bundle of the straight pull testing as below a certain value.
A Yes.
Q For example, number 2 FiberWire, it says 24.
A Correct.
Q In the exhibit, 316, chart, it lists the minimum straight pull for number 2 FiberWire as 32.99; correct?
A Correct.
Q Do you know why the difference?
A No.
Q Is the Exhibit 315 criteria, is that a criteria that Pearsalls ever applied?

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A No.
Q Pearsalls has applied the criteria in Exhibit 316?
A Yes.
Q Is the criteria in Exhibit 316 what Pearsalls applied against the measured test data that obtains for each batch?
A Yes.
Q You understand what I mean by, "Measure test stage data"?
A That it meets that criteria?
Q No, the data itself, measure test stage data. Do you understand what I mean by that?
A No. I don't understand your question.
Q The measure test stage data I am referring to is the, for example, in Exhibit 280, the data at the measure stage.
A Yes.
Q Do you see that?
A Hmm hmm.
Q My question was; does Pearsalls apply the criteria in Exhibit 316 against the data from the measurement test stage?
A Yes.
Q Does Pearsalls apply the criteria in

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Exhibit 316 to the data at any of the other stages, the intermediate, stretch, or dye?
A No.
Q I will show you Exhibit 317. It is a one-page document entitled, "Table 1 Approved FiberWire Constructs", dated September 27th, 2004. Do you recognize Exhibit 317?
(DePuy Mitek Exhibit 317 marked for identification)
A Yes.
Q What is Exhibit 317?
A It is an updated version of the 316.
Q Was Exhibit 317 updated on about September 27th, 2004?
A That's correct.
Q Has Exhibit 317 been applied by Pearsalls as an acceptance criteria since September 27th, 2004?
A That's correct.
Q Has Pearsalls applied Exhibit 317 to the measured test data?
A That's right.
Q It looks like for number 5 FiberWire the values are the same in Exhibit 316 and 317. Is that right?
A Probably, yes.

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Q It looks like FiberWire number 3/4 was added to 317, to Exhibit 317. Is that correct?
A That's correct.
Q FiberWire number 2, it looks like the values change for FiberWire number 2. Is that right?
A Yes.
Q Why?
A I think something was probably altered within the specification.
Q But why does specification for FiberWire number 2 change?
A It probably improved it.
Q Improved the specification?
A Hmm hmm.
Q But why?
A It would have given it more strength.
Q But how did the product -- why did the acceptance criteria change?
MR. TAMBURO: Objection. Asked and answered, and it has already been established this is not a Pearsalls document.
A The values there are governed by what Arthrex has put down.
MR. BONELLA: You don't know why they

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changed it?
A No. Each value changes from each batch.
Q What do you mean by that?
A The break loads can change from one batch to another within -- probably within one or two kilos.
Q The knot strength can vary from one batch to another by 1 or 2 kilos?
A Yes.
Q Why is that?
A Because of the input of the product.
Q What do you mean by that?
A You would get a fluctuation between the raw material.
Q You mean differences in the starting raw material?
A Yes.
Q A change to the knot strength?
A Hmm hmm.
Q It is just a fluctuation in the material?
A Yes.
Q How about the processing?
A The processing, the process stays the same.
Q How about the -- but can the processing

FiberWire Chart: Unit of Force: *Kgf,* Unit of Diameter: *mm*

11/11/2002

Comparison Chart 11-Nov-02		FiberWire # 5				FiberWire # 2	FiberWire # 2	FiberWire # 1	FiberWire # 1
		AR-7210, AR-7211	SP-05-01G	SP-05-01N	SP-05-01W	AR-7200, AR-7202	AR-7201, 2 Strands	AR-7215	AR-7216
		1 Strand, Blue	1 Strand, Green	1 Strand, White	1Strand, B&W	1 Strand, Blue	1 Blue, and 1 B&W	1 Strand, Blue	1 Strand, B&W
		DT PS 07	PSH1	PSH1/1	PSNH1	DT PS 05	DT PSN 05	DT PS 45	DTPSNH 5
Knot Pull	Minimum	29.75	27.80	28.57	26.98	12.87	14.57	10.70	10.42
	Maximum	32.19	30.34	32.88	33.57	14.93	15.71	12.97	14.02
	Mean	**30.86**	**28.93**	**30.64**	**30.05**	**14.03**	**15.15**	**11.70**	**12.10**
Straight Pull	Minimum	58.31	51.46	55.51	48.10	32.99	32.20	26.80	26.31
	Maximum	61.91	58.53	65.29	54.87	36.15	37.21	29.55	28.98
	Mean	**59.66**	**55.56**	**61.34**	**51.96**	**34.70**	**35.04**	**28.17**	**27.83**
Diameter	Minimum	0.769	0.762	0.759	0.764	0.557	0.537	0.467	0.515
	Maximum	0.952	0.940	0.960	0.927	0.665	0.704	0.567	0.586
	Mean	**0.830**	**0.849**	**0.859**	**0.843**	**0.612**	**0.618**	**0.510**	**0.541**

Comparison Chart 11-Nov-02		FiberWire # 2-0	FiberWire # 3-0	FiberWire # 4-0
		AR-7220, AR-7221	AR-7225	AR-7228
		1 Strand, Blue	1 Strand, Blue	1 Strand, Blue
		DT PS 12/2	DT PS 31	DT PS 30
Knot Pull	Minimum	5.19	2.06	1.64
	Maximum	6.53	2.38	1.90
	Mean	**5.65**	**2.26**	**1.78**
Straight Pull	Minimum	12.20	6.10	5.75
	Maximum	14.78	6.62	6.42
	Mean	**13.53**	**6.39**	**6.01**
Diameter	Minimum	0.309	0.219	0.196
	Maximum	0.430	0.275	0.271
	Mean	**0.366**	**0.245**	**0.228**

DEPUY MITEK
EXHIBIT 316
04cv12457

EXHIBIT 25

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE
IN AND FOR THE NEW CASTLE COUNTY

DEPUY MITEK, INC., a Massachusetts Corporation, Plaintiff, v. ARTHREX, INC., a Delaware Corporation, Defendant.	Civil Action No. 04-12457 PBS

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UNITED KINGDOM

on
12th January 2006

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affect the testing results, the knot strength testing results?
A Not generally it doesn't.
Q How about the testing? Can the testing show variations in the testing results?
A Sometimes, yes.
Q But you don't know for sure why the specifications changed?
MR. TAMBURO: Objection. Asked and answered.
A No.
MR. BONELLA: In Exhibit 316, do you see the second column under number 5 FiberWire lists a green product?
A Yes.
Q Similarly, Exhibit 317, the second column lists a green number 5 FiberWire. Do you see that?
A Yes.
Q Has Pearsalls manufactured green number 5 FiberWire for commercial use?
A No.
Q The products shown on Exhibit 316, have they all been manufactured for commercial use other than the green FiberWire, number 5?
A Yes.

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Q How about Exhibit 317? Other than the green number 5 FiberWire, have all those other products been manufactured for commercial use?
A Whether they have been used for commercial use, I don't really know, but these have been given those references in case -- the product has been made, and that is how they would order it.
Q They would order it -- Arthrex orders it by the Pearsalls number?
A PS.
Q For example, Arthrex would order number 5 FiberWire but specifying DTPS 07?
A That's correct.
Q Next I will show you Exhibit 318. It is a two-page document produced to us this morning labeled, "Arthrex Products, Matrix of Label Product and Development Codes". Do you recognize Exhibit 318?
(DePuy Mitek Exhibit 318 marked for identification)
A Yes.
Q What is Exhibit 318?
A What is it?
Q Yes.
A It is a matrix both for the development and products for the use of FiberWire and TigerWire

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Q Have all the products listed in Exhibit 318 been sold for commercial use?
A I don't know.
Q How was this chart prepared?
A It was prepared by myself and one of the engineers at Arthrex.
Q Who? What Arthrex engineer?
A Tara Shanoville (Phonetic).
Q Why were -- how did you select certain products for entry into this matrix?
A Most of them would have been what they had been regarding.
Q What Arthrex had been ordering?
A Yes.
Q What about what Arthrex didn't order?
A Similarly they were listed.
Q Why were they listed?
A Because it may happen at some time or not.
Q Let's go through the chart, then. The first product, PS 30, has that been manufactured for commercial use?
A Yes.
Q How about the second product, PS C33? Has that been manufactured for commercial use?
A Yes.

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Q How about PS 12/2? Has that been manufactured for commercial use?
MR. TAMBURO: Objection. Mike, is your question, have they been sold commercially, or -- because I think he testified that they are prepared to be sold commercially, so when you say, "Are they for commercial use", it is a little confusing, because they are all really for commercial use, but the question you may want to ask is; have they been sold commercially. I am not sure.
MR. BONELLA: What I am asking, Mr. Hallett, is, typically Pearsalls sells the -- the products just aren't samples, they are providing to Arthrex. They sell the product to -- they actually sell it to RK Manufacturing or to Arthrex?
A They would have gone -- originally they go to Arthrex.
Q They are sold to Arthrex?
A Yes.
Q Not RK?
A They go to RK, but if I made a development they normally go to Arthrex first for verification.
Q Development, but when they are sold, the

Arthrex Products
Matrix of Label Product&Development codes

B Hallett ...NOVEMBER 2005

					Braid - Sleeve			Core				Percentage of Suture (Approx.)		
Suture Spool Label	Pearsalls Product Code	Development construction code	Product	Size	Yarn Type	D'tex	Number of yarns	Yarn Type	D'tex	Number of yarns	Ply	UHMWPE	Polyester	Nylon
4-0B-F/W	37G153000	PS30	Blue Fiberwire	4 / 0	UHMWPE Polyester	55 33	4 4	N/A	N/A	N/A	N/A	62.5%	37.50%	N/A
3-0B-F/W	37G203000	PSC33	Blue Fiberwire	3 / 0	UHMWPE Polyester	55 49	4 4	UHMWPE	55	1	0	58.4%	41.6%	N/A
2-0B-F/W	37G302000	PS12/2	Blue Fiberwire	2 / 0	UHMWPE Polyester	111 61	4 4	UHMWPE	144	1	0	70.7%	29.3%	N/A
0B-F/W	37G351000	DT3.5-3	Blue Fiberwire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
0W-F/W	38G351000	PS3.5-3	White Fiberwire	0	UHMWPE Polyester	111 61	6 6	UHMWPE	217	1	0	70.7%	29.3%	N/A
1B-F/W	37G401000	PS53	Blue Fiberwire	1	UHMWPE Polyester	144 113	6 6	UHMWPE	144	1	3	65.7%	34.3%	N/A
1W-T/W	36G401000	PS54	White Tigerwire	1	UHMWPE Polyester Nylon	144 95 78	6 5 1	UHMWPE	144	1	3	70.1%	25.7%	4.2%
1B-T/W	36G401000BLUE	PS55	Blue Tigerwire	1	UHMWPE Polyester Nylon	144 95 78	6 5 1	UHMWPE	144	1	3	70.1%	25.7%	4.2%
2B-F/W	37G500500	PS05T2	Blue Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-F/W	38G500500	PSO5W	White Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
2W-T/W	36G500500	PSN14Na	White Tigerwire	2	UHMWPE Polyester Nylon	144 95 78	8 7 1	UHMWPE	144	1	3	68.1%	28.6%	3.4%
U/T 2W-FW	38A500500	PS05WU-a	White untreated Fiberwire	2	UHMWPE Polyester	144 95	8 8	UHMWPE	144	1	3	67.6%	32.4%	N/A
5B-F/W	37G700250	PS07	Blue Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-F/W	38G700250	PSH 1/1	White Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
5W-T/W	36G700250	PSNH 1	White Tigerwire	5	UHMWPE Polyester Nylon	217 190 78	8 6 2	UHMWPE	217	2	3	70.1%	26.3%	3.6%
See Note Below	See Note Below	PSH 1	Green Fiberwire	5	UHMWPE Polyester	217 190	8 8	UHMWPE	217	2	3	66.7%	33.3%	N/A
3+4W-FW	38A600500	PS 34	White Fiberwire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A
3+4B-FW	38G600500	PS 34A	Blue Fiberwire	3/4	UHMWPE Polyester	217 190	6 6	UHMWPE	144	1	3	60.3%	39.7%	N/A

See Note Below	See Note Below	PS67A	White / Black TigerTail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
See Note Below	See Note Below	PS67B	Blue / Black TigerTail	1	UHMWPE Polyester Nylon	144 95 78	6 6 1	UHMWPE	144	1	3	66.7%	29.3%	4.0%
2W-T/T-46 2W-T/T-54	PSDH5-38 PSDH3-38	PSDH5-38A PSDH3-38A	White / Black TigerTail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
2B-T/T-46 2B-T/T-54	PSDH5-38 PSDH3-38	PSDH5-38B PSDH3-38B	Blue / Black TigerTail	2	UHMWPE Polyester Nylon	144 95 78	8 8 1	UHMWPE	144	1	3	65.4%	31.4%	3.2%
SPD-02-01B	95G-500-500	DPM1	Blue Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01W	96G-500-500	DPM02	White Fiberwire	2	PURITY Polyester	110 113	8 8	PURITY	165	1	3	60.3%	39.7%	N/A
SPD-02-01TW	97G-500-500	DPM03	White Tigerwire	2	PURITY Polyester Nylon	110 113 78	8 7 1	PURITY	165	1	3	61.3%	35.2%	3.5%

FiberWire is a suture with an outer covering of Ultra High Molecular Weight Polyethylene (UHMWPE) and polyester braided over an UHMWPE core.
TigerWire is a version of white FiberWire suture with a black strand creating spiral markings along the entire length of the suture.
TigerTail is a version of FiberWire suture with a black strand that creates spiral markings along one-half the length of the suture.

NOTE
Suture Spool Label and Pearsalls Product Code have not been assigned to these products.

PRODUCT CODE IDENTIFICATION

UNTREATED	A	
MED COATED	G	
BLUE	37	
WHITE	38	
TIGERWIRE	36	Please state blue if required